SUPPORTING THE COMMISSION IN DEVELOPING AN ESSENTIAL USE CONCEPT

FINAL REPORT

Written by Kastalie Bougas, Kristina Flexman, Ian Keyte, Caspar Corden
March 2023

Environment

EUROPEAN COMMISSION

Directorate-General for Environment
Directorate B – Circular Economy
Unit B.2 – Safe and Sustainable Chemicals
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Directorate-General for Environment

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Supporting the Commission in developing an essential use concept

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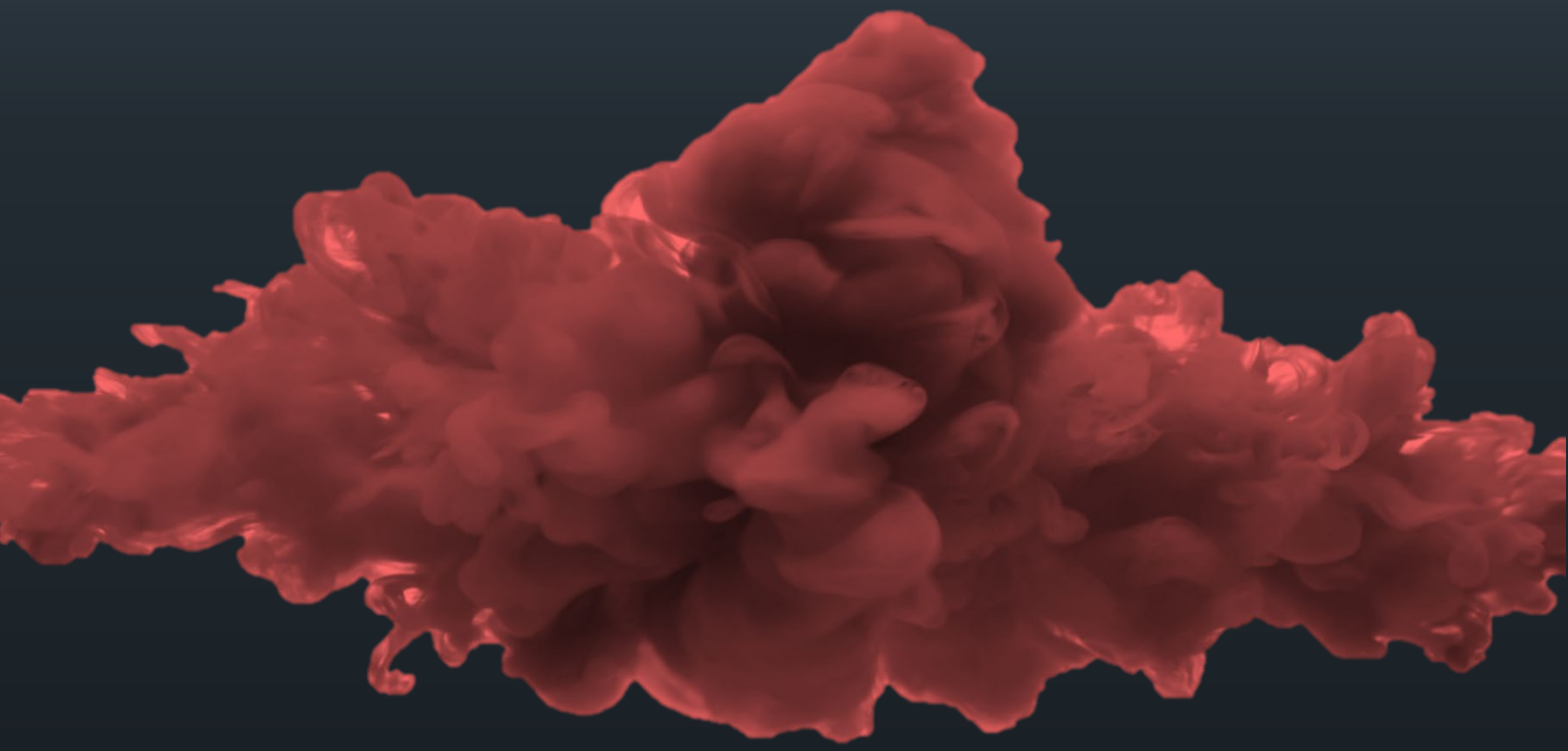

WSP Environment & Infrastructure Solutions GmbH – March 2023

Report for

Petra Ekblom
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Brussels, Belgium

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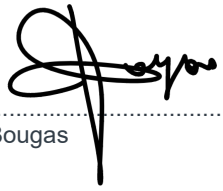

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1	Final report	7/12/2022
2	Revised final report	25/1/2023
3	Revised final report	9/3/2023

Abstract

EN

This report presents the outcome of a project to support the Commission to further define the essential use concept and associated criteria to help phase out the most harmful chemicals. The report investigates how the essential use concept could be implemented in EU legislation including REACH, the Restriction of Hazardous Substances Directive, food contact materials legislation, the Cosmetic Products Regulation, the Taxonomy Regulation, and the End-of-life Vehicles Directive. For REACH, the report identifies 'sub-options' for the essential use concept which could apply within options for the reform of authorisation and restriction, as considered in the targeted revision of REACH. Finally, the report provides a qualitative assessment of expected impacts from the introduction of the essential use concept in REACH. The evidence base was built up through a review of legislation and literature; a targeted survey; interviews; and a workshop.

FR

Ce rapport présente les résultats d'un projet visant à aider la Commission à mieux définir le concept d'utilisation essentielle et les critères associés à ce concept. Le rapport examine comment le concept d'utilisation essentielle pourrait être mis en œuvre dans la législation de l'UE, notamment REACH, la directive sur la limitation des substances dangereuses, la législation sur les matériaux en contact avec les aliments, le règlement sur les produits cosmétiques, le règlement sur la taxonomie et la directive sur les véhicules hors d'usage. Pour REACH, le rapport identifie des «sous-options» pour le concept d'utilisation essentielle qui pourraient s'appliquer dans le cadre des options pour la réforme des processus d'autorisation et de restriction, telles qu'envisagées dans la révision ciblée de REACH. Enfin, le rapport fournit une évaluation qualitative des impacts attendus de l'introduction du concept d'utilisation essentielle dans REACH. Les recherches et consultations menées pour l'élaboration du rapport incluent une analyse de la législation et de la littérature ; une enquête ciblée; des entretiens ; et une conférence.

DE

In diesem Bericht werden die Ergebnisse eines Projekts vorgestellt, mit dem die Kommission bei der weiteren Festlegung des Konzepts der "wesentlichen Verwendungszwecke" und der damit verbundenen Kriterien unterstützt werden soll. Dieser Bericht untersucht, wie das „Essential Use"-Konzept in der EU-Gesetzgebung einschließlich REACH, der Richtlinie zur Beschränkung gefährlicher Stoffe, der Gesetzgebung zu Lebensmittelkontaktmaterialien, der Verordnung über kosmetische Mittel, der Taxonomie-Verordnung und der Altfahrzeuge-Richtlinie umgesetzt werden könnte. In Bezug auf REACH identifiziert der Bericht „Unteroptionen" für das „Essential Use"-Konzept, die innerhalb der Optionen für die Reform der Zulassung und Beschränkung gelten könnten, wie sie in der gezielten Überarbeitung von REACH in Betracht gezogen werden. Schließlich bietet der Bericht eine qualitative Bewertung der erwarteten Auswirkungen der Einführung des „Essential Use"-Konzepts in REACH. Die Evidenzbasis wurde durch eine Durchsicht der Gesetzgebung und der Fachliteratur, eine gezielte Umfrage, Befragungen und einen Workshop aufgebaut.

Executive Summary

Objectives of the project

The objective of this project was to assist the European Commission in the development and operation of a horizontal[1] 'essential use concept' to be applied in EU legislation and feed into the following areas of work: 1) a Commission document on the horizontal criteria and application of the essential use concept across legislation; 2) the amendment of REACH[2]; and 3) the revision processes of other pieces of chemicals legislation, where relevant. The work was carried out by WSP (formerly Wood E&IS GmbH), in collaboration with Ramboll and additional scientific advisors.

Background

The European Commission sets out a commitment in the Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (CSS) to "*define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health*"[3]. This commitment is the basis for the development of an essential use concept and accompanying criteria to guide the application across all relevant EU legislation.

Variations of an essential use concept have been used to a limited extent in existing policies and legislation, in the EU and globally. Most notably, the concept is used under the Montreal Protocol[4] which has seen the phasing out of 98% of ozone-depleting substances between 1989 and 2019. The Montreal Protocol (implemented in EU law by the Ozone Depleting Substances Regulation[5]) is considered as the most successful international environmental agreement.

The overall aim of the essential use concept in EU legislation would be to allow systematic decision-making to facilitate the phasing out of the most harmful chemicals by only allowing them when their use is essential for society. The concept has the potential to protect the environment and human health from the most harmful chemicals by facilitating the phase out of non-essential uses and therefore preventing potential human and environmental exposure to the most harmful chemicals, while allowing more time for phasing out these substances in essential uses.

The ongoing work for the revision of REACH, and of some other pieces of chemicals legislation, presents an opportunity to improve existing regulatory processes. Improving processes to phase out the use of the most harmful chemicals is imperative given the current challenges in chemical regulation, for example, complex and slow restriction processes and heavy authorisation procedures under REACH. These limitations can delay decisions and actions to adopt appropriate risk management measures for the most harmful chemicals, and therefore can result in exposure of citizens and workers as well as the release of the most harmful chemicals to the environment.

[1] I.e., applicable across legislation affecting different sectors / industries and environmental subject areas.
[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.
[3] European Commission (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM(2020) 667. 14 October 2020.
[4] United Nations Environment Programme, UNEP. The Montreal Protocol on Substances that Deplete the Ozone Layer, Decision IV/25: Essential uses. Retrieved 2022-11-22 at: https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses#:~:text=the%20Ozone%20Layer-,The%20Montreal%20Protocol%20on%20Substances%20that%20Deplete%20the%20Ozone%20Layer,consumption%20of%20ozone%2Ddepleting%20substances.
[5] Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer

Approach taken

The tasks conducted under this project included the identification of relevant existing EU chemicals legislation that already contains, or may benefit from, an essential use concept; the analysis of legislation, definitions, and terminology, and a review of additional sources; the development and refinement of the most appropriate definitions and criteria for an essential use concept and the main elements needed to apply these to legislation; the analysis and refinement of policy options for application and operation of an essential use concept in practice (specifically for REACH and in more general terms for selected pieces of legislation); the development of case studies to assess how the proposed essential use concept would have operated in practice in previous cases of restrictions or authorisations of chemicals, and; an investigation of the potential impacts from introducing the concept in REACH.

A wide stakeholder consultation was conducted as a transversal task to support the overall outputs of the project. The consultation activities involved EU institutions, Member States authorities/agencies, industry associations, businesses, academia, research institutions and consumer organisations. The activities comprised:

- An **online stakeholder workshop** with over **650 participants** (including 125 partaking in smaller group discussions) was held in March 2022 to collect stakeholder views to inform further development of the essential use concept and consider how the concept could be operationalised in REACH and other relevant legislation.
- A **targeted survey** (**163 respondents**) was launched on 13 April 2022 and ran until 4 May 2022 to gather suggestions for how to develop and implement the essential use concept horizontally, under REACH, and under other legislation.
- A total of **32 interviews** were held with stakeholders to provide them with the opportunity to elaborate on their views.
- Within the **public consultation for the overall revision of REACH**, respondents were asked about the benefits and costs expected from implementation of an essential use concept in REACH.

Key findings and conclusions

Horizontal essential use concept

Scope of the essential use concept

The essential use concept should only apply to the **uses** of the **most harmful chemicals** which are a priority for phasing out, as referred to in the CSS[6].

A ‘use’ is defined under REACH Article 3 as any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. Contextualising the use in terms of its necessity for health or safety / criticality for the functioning of society is imperative, and therefore consideration of the use in terms of the **need for the technical function provided by the most harmful chemical for a specific end use (e.g. a final product used by consumers or professionals[7]) in a particular setting** is required to discern essentiality for society.

[6] Chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bio-accumulative, as well as chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ.

[7] Uses where the substances are incorporated *in* the product, as well as uses of substances to produce the final product but where the substances *do not remain in the product* itself, may be considered.

The essential use concept is intended to be horizontal so that it could apply to any sector (although affected sectors and substances will depend on whether, and to what extent, certain pieces of legislation adopt the concept). Specific uses of one of the most harmful chemicals within any sector could be essential or non-essential for society, therefore a case-by-case assessment is needed. Applying the concept in a sweeping fashion could have negative consequences, e.g. allowing all uses in an 'essential sector' could allow uses of the most harmful chemicals which are not critical for the functioning of society and/or necessary for health/safety, as well as those which are substitutable. In addition, prohibiting all uses in 'non-essential sectors' could result in significant market disruption as well as withdrawal of uses which are necessary for health, safety and/or critical for the functioning of society.

Definition of the essential use concept

Limited definitions related to the essential use concept were identified through the information gathering tasks. For example, even where the concept has been applied in the past (e.g. under the Montreal Protocol), there is no further guidance to explain criteria or definitions. As such, this report already goes one step further to reduce subjectivity.

In order to further define the essential use concept and associated criteria, there is a need to strike an appropriate balance between granularity, stringency, and flexibility. For example, too narrow criteria could be short-sighted and lead to discrimination against products or sectors or failure to respond to changing societal needs. On the other hand, too general criteria could allow too many uses of the most harmful chemicals to be assessed as essential for society. To minimise these risks, we conclude that: 1) criteria should be retained as set out in the CSS; 2) horizontal guidance should bring further definition and consistency in application of these criteria across legislation; and 3) legislation-specific guidance should be developed as required.

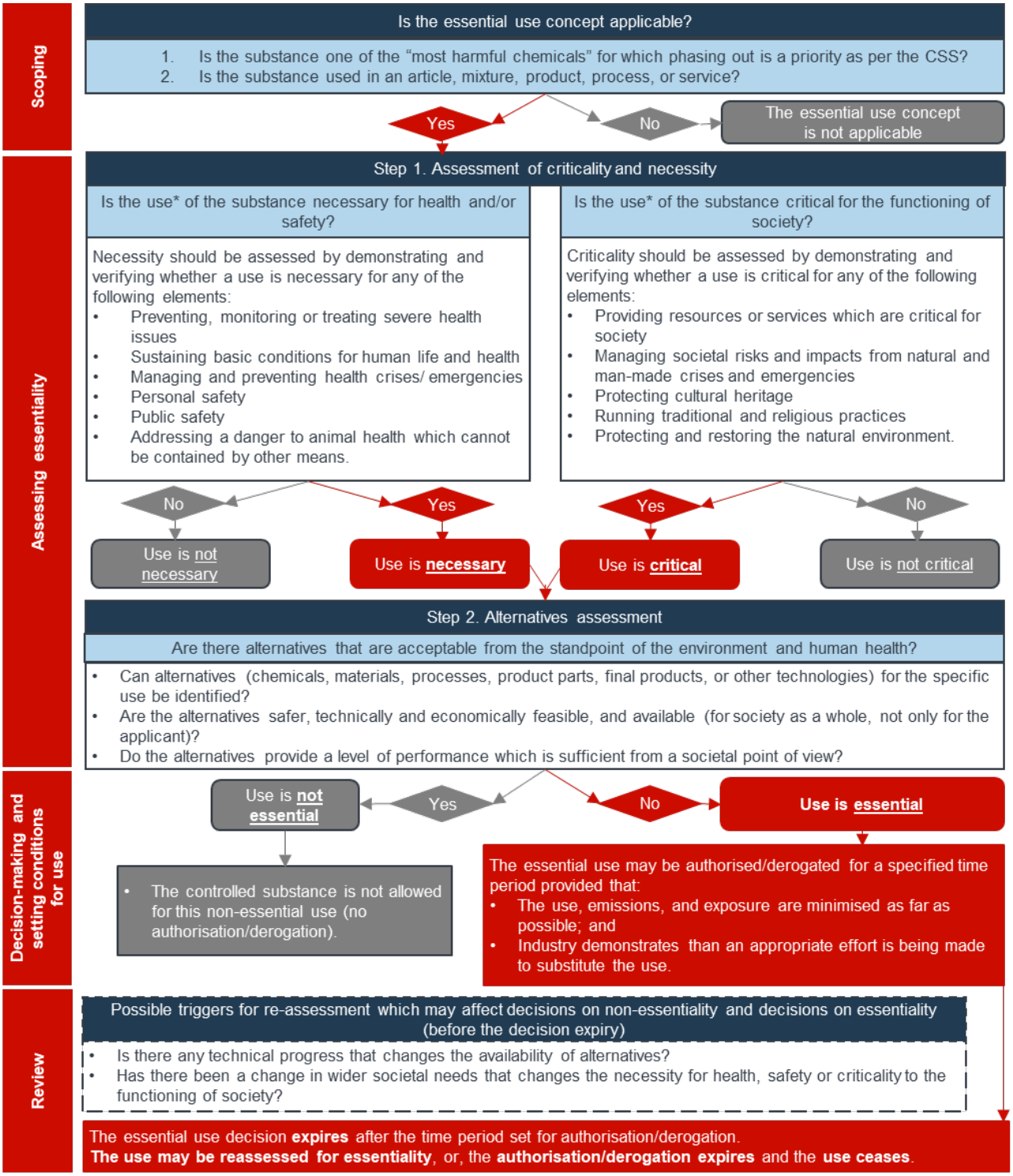
1. The **criteria** for a use of a substance to be defined as 'essential' for society (as per the CSS) require that the use is:
    - necessary for health, safety AND/OR critical for the functioning of society
    - AND there are no alternatives that are acceptable from the standpoint of environment and health.
2. A **horizontal guidance** would bring further clarity, specificity, and consistency in the application of the criteria across different pieces of legislation.

A horizontal guidance document could limit subjectivity in the implementation of the concept across legislation, improving predictability, effectiveness, efficiency, and coherence. The main benefit of providing details in guidance rather than in the criteria is that it allows flexibility, allowing for a degree of political steer, while still providing stakeholders with a level of detail which makes the criteria interpretable and implementable in a practical way.

3. The development of **legislation-specific guidance**, as required, would reflect nuances in how the essential use concept is introduced in practice into each piece of legislation.

For uses derogated from restriction / authorised based on essentiality for society, we conclude that: conditions must be set to ensure that the use of, and the human and environmental exposure to, the most harmful chemical are minimised; substitution with safer alternatives is incentivised; decisions that uses are essential for society are reviewed after a time period (established on a case-by-case basis) to discern whether the use still qualifies as essential for society; and time periods define cut-off dates for new applications and end dates for existing applications.

The figure below represents high-level overview of the horizontal essential use concept, as developed under this project.



* Use should be assessed through considering the societal need for the technical function provided by the most harmful chemical in a specific end use (e.g. final product) in a defined setting.

Essential use concept across EU legislation

The essential use criteria are intended to be applicable horizontally across relevant EU legislation. This report investigates how the essential use concept could be implemented in REACH and in more general terms in other EU legislation including the Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU), food contact materials legislation (e.g. Regulation (EU) No 10/2011), the Toy Safety Directive (2009/48/EC), the Cosmetic Products Regulation (1223/2009/EC), the Taxonomy Regulation (2020/852/EU), and the End-of-life Vehicles Directive (2000/53/EC), based on legislation reviews as well as inputs from stakeholders as part of the consultation activities. Developing policy options and assessing the impacts of implementing the essential use concept in these pieces of legislation is beyond the scope of this project and would require separate impact assessments.

Essential use concept in REACH

Objectives and legal basis

The implementation of the essential use concept in REACH is to be considered in the context of the reform of REACH authorisations and restrictions. It is envisaged that the essential use concept within generic and specific risk management approaches[8] can provide a tool for progressive phasing out of the most harmful chemicals, primarily in non-essential uses, and secondarily in essential uses which may become non-essential over time. The essential use concept is intended to bring more simplicity, transparency, predictability and efficiency in authorisation decisions and derogations from restrictions. The concept is intended to prevent the use of the most harmful chemicals for non-essential uses by changing the approach for justifying exemptions from restrictions and justifying the granting of authorisations. Furthermore, the concept is intended to minimise essential uses, as well as their associated exposure and risks to human health and the environment to as low level as possible. Lastly, the concept is intended to encourage substitution of essential uses by requiring industry to demonstrate that appropriate effort is being made to develop and use alternatives.

Options and other parameters

Depending on the preferred option for the reform of authorisation and restriction (to be identified by the Commission based on the technical support study[9]), the essential use concept could apply as a basis for granting authorisations (Article 60) and/or derogation from restrictions under both Article 68(1) and 68(2).

The following sub-options were considered for the essential use concept:

- **Sub-option A**: Non-binding guidance for the introduction of the essential use concept in authorisation and restriction, as an optional consideration, complementary to current provisions.
- **Sub-option B**: Binding implementing regulation and supporting guidance for the introduction of the essential use concept in authorisation and restriction, as an optional consideration, complementary to current provisions.

[8] Annex 8 - Section 8.2.1 of the fitness check on most relevant chemicals legislation further expands upon the differences between generic and specific risk assessments: European Commission (2019). Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. COM(2019)264. 18 July 2019.
[9] Valdani Vicari & Associati, VVA (Unpublished). 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: Impact Assessment, Third Draft Final Report [06/09/2022]

- **Sub-option C**: Introduction of legal changes in REACH for essential use under authorisation and restriction, with the essential use concept being **a complementary approach to the socio-economic (SEA) route and adequate control route (ACR)** to decide on authorisations. The essential use concept would be used to decide on all derogations from restrictions.
- **Sub-option D**: Introduction of legal changes in REACH for essential use under authorisation and restriction, with the essential use concept **replacing the socio-economic route** as an approach to decide on authorisations and derogations from restriction. In addition, the **adequate control route for authorisation would be removed,** so that all applications for authorisation and derogations from restriction would be based on the essential use concept.

The options have been described in this report to show potential entry routes (within authorisation and restriction processes) for the essential use concept in REACH, as well as various ways for implementation. Sub-options A and B would both result in optional consideration of the essential use concept alongside the current provisions for derogations from restrictions and authorisations. Sub-option C would see mandatory application of the essential use concept for derogations from restrictions and optional consideration of the essential use concept for authorisations. Sub-option D would see full replacement of the current criteria used for derogations from restrictions and authorisations with the essential use concept, so that only essential uses of the most harmful chemicals could be derogated or authorised.

Main impacts from options

Under all options, the essential use concept would be expected to reduce the number of derogations from restriction and authorisations of the most harmful chemicals. It would also encourage substitution and require emissions and exposure from derogated/authorised uses of the most harmful chemicals to be minimised. Consequently, positive impacts would be expected on the environment and human health from improved protection against the most harmful chemicals. These could not be quantified under this project.

The essential use concept would be intended to make authorisation and restriction processes simpler, less burdensome, and therefore less costly for both authorities and industry, however, there is a high level of uncertainty regarding the economic impacts. For example, information required to demonstrate essentiality may be more or less difficult to gather and analyse in comparison to current information requirements for authorisations and restriction derogations (e.g. socioeconomic data). This would likely vary on a case-by-case basis. It is expected (with uncertainty) that the information requirements would be easier to fulfil, decisions would be easier to make. Applicants could be deterred from applying for authorisations or derogations from restrictions for uses likely to be deemed non-essential for society, saving administrative costs of applications. Economic costs to industry from lost production of substances for non-essential uses could be substantial, although where alternatives are available, these costs would be shifted to profits to providers of safer alternatives.

The analysis of impacts and comparison of the sub-options in this report serve to provide support to the Commission for the impact assessment of the REACH revision.

List of abbreviations

Abbreviation	Meaning
ACR	Adequate control route
BKK	Germany's Federal Office of Civil Protection and Disaster Assistance
BPR	Biocidal Products Regulation (Regulation (EU) 528/2012)
BRT	Better Regulation Toolbox
CARACAL	Competent Authorities for REACH and CLP expert group
CFC-113	Chlorofluorocarbon-113
CI	Critical infrastructure
CLP	Regulation on classification, labelling and packaging of substances and mixtures (Regulation (EC) No 1272/2008)
CLRTAP	Convention on Long Range Transport of Air Pollution
CMR	Carcinogenic, mutagenic, reprotoxic
COM	European Commission
CPR	Cosmetic Products Regulation (Regulation (EC) No. 1223/2009)
CSS	Chemicals Strategy for Sustainability Towards a Toxic-Free Environment
DEHP	Di (2-ethylhexyl)phthalate
DG	Directorate General
DNEL	Derived No-Effect Level
DNSH	Do Not Significant Harm
EAC	Equivalent annual cost
EASA	European Aviation Space Agency
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Agency
ELV	End-of-Life Vehicle Directive (Directive 2000/53/EC)
EMA	European Medicines Agency
ESA	European Space Agency
EU	European Union

Abbreviation	Meaning
FAO	Food and Agriculture Organisation
FCM	Food contact materials
GCO	Global Chemicals Outlook
GHS	Global harmonized system
GMP	Good manufacturing practice
GRA	Generic approach to risk management
HBCDD	Hexabromocyclododecane
ICCM	International Conference on Chemicals Management
ILO	International Labour Organisation
MS	Member State
MSC	Member State Committee
MSCA	Member State Competent Authority
NGO	Non-governmental organisation
NPE	Nonylphenol ethoxylates
ODS	Ozone Depleting Substance Regulation (Regulation (EC) 1005/2009)
OPE	Octylphenol ethoxylates
PBT	Persistent, bioaccumulative, toxic
PFAS	Per- and polyfluoroalkyl substances
PFOA	Perfluorooctanoic acid
PMT	Persistent, mobile, toxic
PNEC	Predicted no-effect concentration
PIR	Polyisocyanurate
PUR	Polyurethane rigid foam
RAC	Risk Assessment Committee
REACH	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of chemicals (Regulation (EC) No 1907/2006)
RoHS	Restriction of Hazardous Substances Directive (Directive 2011/65/EU)
SAICM	Strategic Approach to International Chemicals Management
SCCS	Scientific Committee on Consumer Safety

Abbreviation	Meaning
SCIP	Database for information on Substances of Concern In articles as such or in complex objects (Products)
SDG	Sustainable Development Goals
SEA	Socio-economic analysis
SEAC	Socio-Economic Analysis Committee
SRA	Specific risk assessment
SVHC	Substance of very high concern
SWD	Staff working document
TFEU	Treaty for the European Union
TSD	Toy Safety Directive (Directive 2009/48/EC)
UN	United Nations
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organisation
US	United States
UV	Ultraviolet
vPvB	Very persistent very bioaccumulative
vPvM	Very persistent very mobile
WEEE	Waste Electrical and Electronic Equipment Directive (Directive 2012/19/EU)
WHO	World Health Organisation

Contents

Part A

Introduction and approach

1. Introduction

1.1 This report

This is the **final report** for the project supporting the European Commission in developing an essential use concept. WSP (formerly Wood E&IS GmbH), in collaboration with Ramboll and additional scientific advisors, has been contracted by the Commission to assist in the development and operation of a horizontal 'essential use concept' to be applied in EU legislation. This report provides the final outputs of the project.

1.1.1 Structure of report and coverage of tasks within report

Part A of the report (this part) covers the background to the project, including the context, objectives, and methodology. Key project outputs are covered in Parts B and C.

Part B covers the horizontal essential use concept, including supporting evidence and conclusions for criteria, as well as case studies, and a discussion on the potential the introduction of the essential use concept in EU legislation other than REACH.

Part C assesses policy options for the essential use concept in the context of REACH[10]. This is set out in the format of an Impact Assessment report in line with the Better Regulation Toolbox[11] guidance:

- Section 6 sets out the political and legal context;
- Section 7 sets out the problem definition;
- Section 8 sets out why should the EU act;
- Section 9 sets out the objectives of the intervention;
- Section 10 sets out the available options to achieve the objectives;
- Section 11 sets out the impacts of the essential use concept, including who would be affected; and
- Section 12 sets out a comparison between the options.

The information gathering tasks (Task 1 on screening legislation, 2 on information gathering and analysis, and 5 on consultation) have been used to feed into all sections of the report. Part B covers the outputs of Task 3 on refining the criteria, , case studies, and investigating in general terms the introduction of the essential use concept for (non-REACH) EU legislation. Part C covers the outputs of Task 4 (policy options and impact assessment for REACH). Supplementary information is provided in appendices, providing the specific outputs of individual tasks.

[10] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
[11] European Commission (2021). Better Regulation Guidelines, Retrieved 2022-11-22 at: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en.

1.2 Policy background and context

The Chemicals Strategy for Sustainability Towards a Toxic-Free Environment[12] (CSS) proposes the development of a horizontal[13] essential use concept to apply across all relevant EU legislation. The Commission sets out a commitment in the CSS to "*define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health*".

The development of an essential use concept is aligned with the EU ambition for a toxic-free environment, which is highlighted as a priority in a number of policy strategies including the European Green Deal[14], the CSS, the Zero Pollution Action Plan[15], and the Circular Economy Action Plan[16]. The concept would contribute to reductions in the use, and consequently the emissions, risks, and impacts associated with most harmful chemicals. The concept has the potential to protect the environment and human health from the most harmful chemicals by facilitating the phase out of non-essential uses and therefore preventing potential human and environmental exposure to the most harmful chemicals, while allowing more time for phasing out these substances in essential uses.

The overall aim of the essential use concept is to allow systematic decision-making to facilitate the phasing out of the most harmful chemicals by only allowing them when their use is proven essential for society, i.e., necessary for health and/or safety or critical for the functioning of society and if there are no acceptable alternatives from the standpoint of human health and the environment. A similar concept has been used under the Montreal Protocol[17] which saw the phasing out of 98% of ozone-depleting substances between 1989 and 2019 and is considered as the most successful international environmental agreement.

The concept has been investigated for further use in EU chemicals legislation, for example, Cousins et al. (2019) suggested the application of the concept to assess the essentiality of certain uses of PFAS (a large group of very persistent substances which are known to cause harm to the environment and human health).[18]

The ongoing work for the revision of REACH, and of some other pieces of chemical's legislation, presents an opportunity to improve existing chemical regulatory processes. Improving processes to phase out the use of the most harmful chemicals is imperative given the current challenges in chemical regulation, for example, complex and slow restriction processes and heavy authorisation procedures under REACH. These limitations can delay decisions and actions to adopt appropriate

[12] European Commission (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. 14 October 2020.
[13] I.e., applicable across legislation affecting different sectors / industries and environmental subject areas.
[14] European Commission (2019). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM(2019) 640. 11 December 2019.
[15] European Commission (2021). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil', COM(2021)400. 12 May 2021.
[16] European Commission (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A new Circular Economy Action Plan For a cleaner and more competitive Europe, COM(2020)98. 11 March 2020.
[17] United Nations Environmental Programme, UNEP. The Montreal Protocol on Substances that Deplete the Ozone Layer, Decision IV/25: Essential uses. Retrieved 2022-11-22 at: https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses#:~:text=the%20Ozone%20Layer-,The%20Montreal%20Protocol%20on%20Substances%20that%20Deplete%20the%20Ozone%20Layer,consumption%20of%20ozone%2Ddepleting%20substances.
[18] Cousins, I.T.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Ng, C.A.; Patton, S.; Scheringer, M.; Trier, X.; Vierke, L.; Wang, Z.; DeWitt, J.C. (2019), The concept of essential use for determining when uses of PFASs can be phased out. *Environmental Science: Processes & Impacts, 21, 1803-1815.*

risk management measures for the most harmful chemicals, and therefore can result in exposure of citizens and workers[19] as well as the release of the most harmful chemicals to the environment.

An essential use concept could help address the limitations in current chemicals legislation by introducing criteria to allow justification to be made in the decision making on discontinuing uses of these substances. These criteria would be expected to introduce more simplicity, transparency, predictability, and efficiency in the assessment of derogations to restrictions and authorisations, to prevent uses that are not proven essential for society and to provide more regulatory certainty to businesses. It is acknowledged that a horizontal application of the concept could have far-reaching consequences compared to the current system and, therefore, it is key to involve and consult the various actors affected and/or active in the field of chemicals legislation. The development and application of an essential use concept is intended to encourage innovation in safe and sustainable chemicals to be used as alternatives to the most harmful chemicals.

Other than the Montreal Protocol, which covers a very defined set of substances, there has been little practical application of the essential use concept in chemicals policy to date. It is therefore important to understand how the above potential benefits would be realised in practice and also what the costs will be.

1.3 Objectives of project

The overall objective of this project is to assist the Commission in the development and operation of an 'essential use concept' to be applied in EU legislation, in alignment with the commitment set out in the CSS (as described above).

The tasks conducted under this project included:

- Screening to identify relevant existing EU chemicals legislation that already contains or may benefit from an essential use concept (Task 1a);
- Screening and mapping key stakeholders to be involved in the consultation (Task 1b);
- Gathering and analysis of information, including an analysis of legislation (Task 2a), analysis of definitions and terminology across different legislation (Task 2b), and a review of additional information sources (Task 2c);
- Developing and refining the most appropriate definitions and criteria for an essential use concept, and the main elements needed to apply this to legislation (Task 3a);
- Analysing and refining the policy options for application and operation of an essential use concept in practice (Task 3b);
- Developing case studies to assess how the essential use concept developed would have operated in practice in previous cases of restrictions or authorisations of chemicals (Task 3c);
- Investigating the potential impacts of introducing the concept in REACH (Task 4); and
- Conducting a targeted stakeholder consultation through interviews, a targeted survey, and a stakeholder workshop (Task 5).

The work carried out under this contract is intended to support the Commission development of an essential use concept, as stipulated by the CSS, and specifically to feed into the following areas of ongoing work: 1) a Commission document on the horizontal criteria and application of the essential

[19] Note that the protection of workers is also covered by a number of pieces of EU legislation other than REACH including the occupational safety and health (OSH) Framework Directive (Directive 89/391 EEC) and the Chemicals OSH legislation (Carcinogens, Mutagens and Reprotoxicants Directive 2004/37/EC, Chemical Agents Directive 98/24/EC and Asbestos at Work Directive 2009/148/EC).

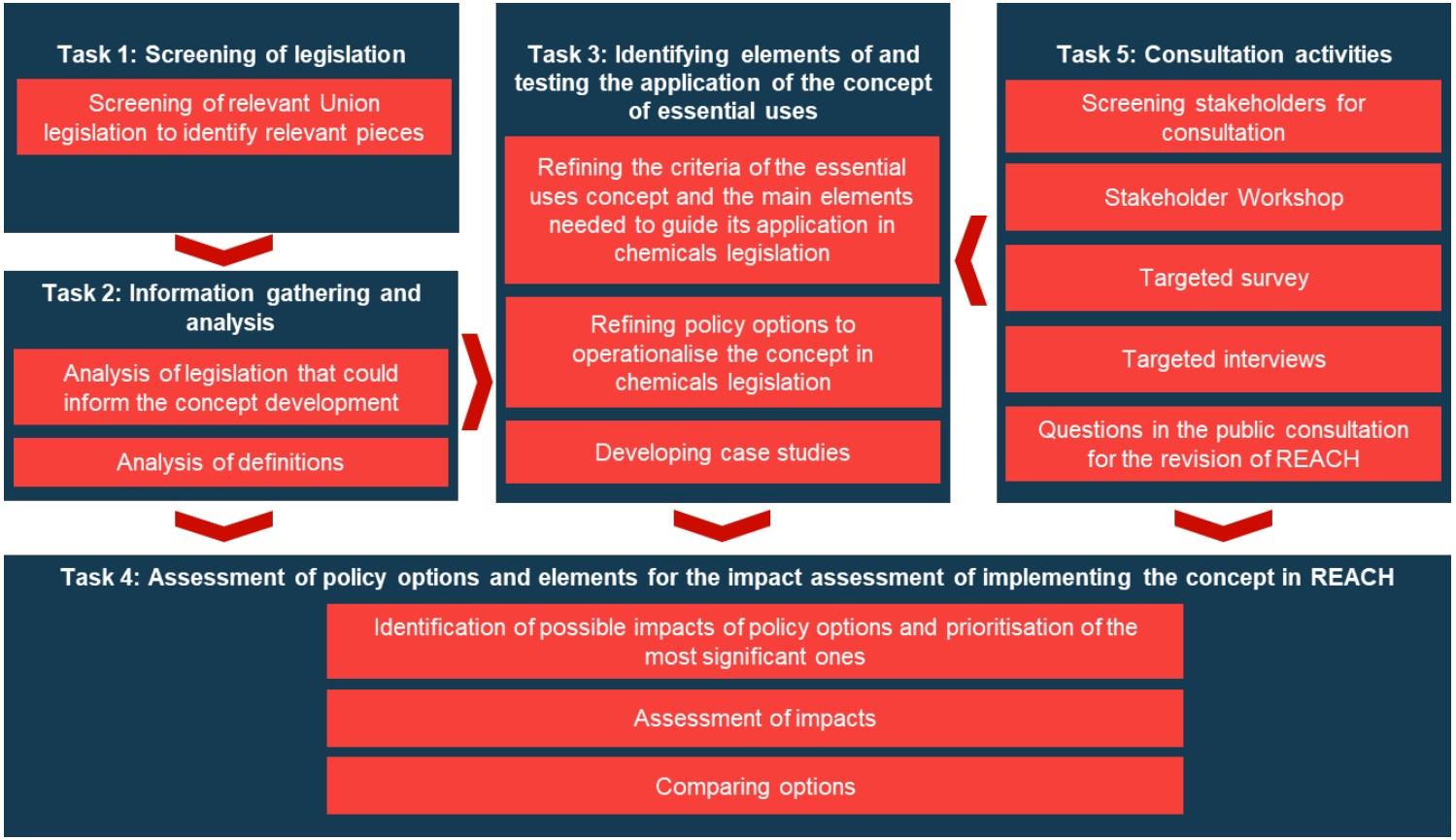
use concept across legislation; 2) the amendment of REACH; and 3) the revision processes of other pieces of legislation, as relevant.

2 Methodology

2.1 Overview of approach

The figure below provides an overview of the main project tasks and highlights their sequential nature.

Figure 2.1 Overview of main project tasks



2.2 Approach taken

This section describes the approach taken, split by task (1 to 5).

2.2.1 Task 1: Screening of legislation

The purpose of the screening of legislation was to provide a solid foundation for the data gathering and analysis underlying this project. This aimed to identify the pieces of EU legislation that already contain (to some degree), or would benefit from, an essential use concept.

The project team conducted a rapid screening of relevant EU chemicals legislation, identified from the Commission Fitness Check of the most relevant chemicals legislation[20] and Fitness Check of endocrine disruptors[21]. This list was further informed by the discussion with the Commission at the project kick-off meeting. The list of legislation covers both 'horizontal' EU legislation (e.g. REACH and CLP), as well as 'vertical' legislation covering the use of chemicals in, and exposure to humans and the environment through consumer, medical and occupational uses, and the emissions of chemicals to the environment (e.g. releases to air and water).

Further information on the legislation screening, including outputs, is detailed in Appendix A.

2.2.2 Task 2: Information gathering and analysis

Task 2 built upon Task 1 by further analysing the legislation identified, and by identifying and screening additional information sources such as legislative guidance documents, non-EU regulations, international agreements, grey literature (e.g. position papers, policy reports), court rulings, and academic publications.

For the pieces of legislation identified under Task 1 that already apply an essential use concept (or similar)[22], the legislative text and related documents were reviewed to extract 'lessons learnt' in defining and applying the essential use concept. The findings were validated through interviews with experts.

The outcome of this Task fed into the development of the horizontal essential use concept and the analysis carried out for the case studies (see Task 3 below).

2.2.3 Task 3: Identifying elements of and testing the application of the essential use concept

Data gathered from the literature under Task 2 was used to help develop and refine the essential use concept to be applicable in practice in EU legislation.

This involved exploring key elements which will need to be addressed to allow the Commission to deploy an essential use concept, e.g. by further defining the essential use criteria and describing policy options to envisage how the concept may be operationalised in REACH.

Policy options for other pieces of legislation were explored in less detail on the basis of the screening carried out under Task 1, recommendations from Commission staff, and contributions from stakeholders.

[20] European Commission (2019). Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. COM(2019)264. 18 July 2019.
[21] European Commission (2020). Fitness Check on endocrine disruptors, SWD(2020)251. 14 October 2020.
[22] These included the Montreal Protocol, ODS Regulation, REACH, Biocidal Products Regulation, Plant Protection Products Regulation, Cosmetic Products Regulation, Toy Safety Directive, Food Contact Materials Regulation, POPs Regulation, RoHS Directive, ELV Directive, and EU Taxonomy legislation.

Case studies were developed to test the criteria by showcasing examples of essentiality and non-essentiality, based on existing examples of derogation and authorisation requests. Case studies can be found in Appendix B.

2.2.4 Task 4: Impact assessment

The main objective of Task 4 was to provide information to support an Impact Assessment considering all relevant economic, social, and environmental impacts of each of the policy options for REACH prioritised in the previous tasks, to feed into Part C of this report. This involved collecting evidence (including from the literature and consultation) to assess if future legislative or non-legislative EU action would be justified and how such action could best be designed to achieve desired policy objectives. The approach followed Chapter 3, Section 2 of the Better Regulation Guidelines[23] on Impact Assessments (on key questions and principles of impact assessment).

Data collected in previous tasks, including from the literature and consultation, was utilised to identify and describe the most significant impacts expected from integrating the essential use concept in REACH.

Impacts were compared against the current situation / no policy change scenario (defined as the baseline), as a reference point to help compare and contrast the costs and benefits of each policy option. Importantly, Task 4 assessed predicted impacts from **changes in the granting of derogations and authorisations** which could be triggered by implementing the essential use concept instead of current processes (e.g. based on socio-economic analysis and adequate control). This is further elaborated in Part C. In the wider context of the REACH revision, changes in how many and which substances would be restricted or subject to authorisation are not considered as impacts from the essential use concept, but of the other measures under the reform of restriction and authorisation which are beyond the scope of this project and have been assessed in parallel by VVA (Unpublished)[24]. Impacts from the essential use concept are considered less significant than impacts from the other changes to authorisation and restriction.

The task was limited by a number of factors which prevented a full (quantitative) analysis of the policy options. Mainly, the final form of policy options for the reform of authorisation and restriction and the map of uses which could become subject to the extended generic approaches to risk management, upon which the full assessment of impacts of the essential use concept would be dependent, only became available towards the end of this project. Additionally, the methodology used and the level of details in the final map of uses did not enable the project team to assess which uses for which substances could qualify as essential or non-essential for society in comparison to which uses could be derogated or authorised under the baseline. This also prevented assessment of how many, and which, uses could be affected by the essential use concept.

2.2.5 Task 5: Consultation

Stakeholder consultation was conducted as a transversal task to support the overall outputs of the project. First, a stakeholder mapping exercise was conducted to identify all key stakeholders / stakeholder groups, to ensure that they were invited to partake in relevant consultation activities and provide inputs to inform the other tasks of the project. The consultation activities included a targeted survey, targeted interviews, a workshop, and a public consultation. Information gathered through all tasks has been triangulated to produce this report.

[23] European Commission (2021). Better Regulation Guidelines, Retrieved 2022-11-17 at: https://ec.europa.eu/info/sites/default/files/swd2021_305_en.pdf

[24] Valdani Vicari & Associati, VVA (Unpublished). 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. Third Draft Final Report [06/09/2022].

Stakeholder mapping

A stakeholder mapping exercise was conducted in line with the Better Regulation Toolbox to ensure that all relevant stakeholder groups/types had a possibility to contribute to the project. All identified stakeholders were invited to the workshop, which was publicised online and open for registration by all stakeholders (for exhaustiveness). All workshop registrants (over 650 registrants) were invited to complete the survey, however, the capacity for smaller group discussions in the workshop and interviews was limited and so only a sample of relevant stakeholders could be invited. The stakeholder mapping exercise was used to inform the selection of this sample in an objective way, aiming to involve a balanced representation of stakeholders as far as possible.

Stakeholders were identified by researching organisations with demonstrated interest/expertise in chemicals regulation, chemicals risk management, and/or the essential use concept, through available publications, stakeholders who directly contacted the project team and/or Commission, and those already known to the project team (based on networks and experience in consulting stakeholders on similar topics).

Prioritisation for consultation activities was undertaken by mapping each stakeholder against the following factors (with respect to the essential use concept): expected type and level of impact on the stakeholder; expected/demonstrated level of interest of the stakeholder; level of stakeholder's expertise; significance of the role that the stakeholder would have in implementing the concept in legislation.

The overall selection of stakeholders was reviewed to ensure a good level of representativeness of all stakeholder types as far as possible.

Workshop

An online stakeholder workshop was held on the 3 March 2022 to gather feedback from stakeholders on the research completed under the project by that point in time. The primary focus of the workshop was on evidence gathering rather than seeking validation of results.

Over 650 participants attended for the workshop and provided inputs via the MS Teams chat and Q&A sessions.

Approximately 125 stakeholders were invited to partake in the break-out sessions in 6 parallel smaller group discussions. Stakeholders for break-out sessions were prioritised with the aim to ensure a balanced representation of stakeholder groups, as far as possible. The stakeholder split for the break-out sessions (total for all groups) was as follows: 42% Member State competent authorities, 32% for private sector, 13% for NGOs, 6% for academia, 5% EU institutions/agencies, and 1% for international organisations.

The key takeaways from the workshop were synthesised into a workshop report[25], detailing common arguments from stakeholders including points of contention and agreement between stakeholders.

Targeted survey

A targeted survey was launched on 13 April 2022 and ran until 4 May 2022 to support this project. The survey was distributed to all participants from the workshop and those identified under the stakeholder mapping. Respondents (163 in total) included representatives from business associations (77), companies/businesses (52), public authorities (13), NGOs (8), academia/research institutions (2), and other (11).

[25] Wood (2022). Supporting the Commission in developing an essential use concept - Workshop report. Retrieved 2022-11-22 at: https://environment.ec.europa.eu/system/files/2022-05/Essential%20Use%20Workshop%20Report%20final.pdf

The survey aimed to gather suggestions for how to develop and implement the essential use concept horizontally, under REACH, and under other legislation.

Targeted interviews

Targeted interviews were held with stakeholders to provide them with the opportunity to elaborate on their views. This included interviews with NGOs (5), Member State authorities/agencies (3), EU institutions/agencies (4), industry associations (8), academia / research institutions (1), and a consumer organisation (1).

Additional interviews (10) were also carried out with representatives from European institutions (DG ENV, DG GROW, DG SANTE), as well as follow-up conversations with industry associations, and an academic/research institution to support the elaboration of the case studies.

Public consultation

Within the public consultation for the overall revision of REACH, respondents were asked about the benefits expected from implementation of an essential use concept in REACH; in terms of environmental benefits, health benefits, socio-economic benefits, economic benefits, and potential benefits to REACH authorisation and restriction processes. These results were used to inform the impact assessment of this project.

Part B

Horizontal essential use concept

3 Criteria for the horizontal essential use concept

3.1 Introduction

The criteria for the essential use concept set out in the CSS require that *the most harmful chemicals are only allowed if:*

> *(1) Their use is* ***necessary*** *for* ***health, safety and/or*** *is* ***critical*** *for the* ***functioning of society****;*
>
> ***and*** *(2) there are* ***no alternatives*** *that are acceptable from the standpoint of* ***environment*** *and* ***health****.*

The CSS states that the Montreal Protocol definition of essential uses, from which the above criteria were inspired, should be taken into account. The Montreal Protocol on Substances that Deplete the Ozone Layer Decision IV/25, paragraph 1,[26] states that a use of a controlled substance should qualify as 'essential' only if it meets the above criteria. In addition, Decision IV/25 specifies that the 'functioning of society' encompasses **cultural and intellectual aspects**, and instead of 'no alternatives' (as noted in the CSS), the second criterion states that there must be 'no **available technically and economically feasible** alternatives or substitutes'.

Decision IV/25 of the Montreal Protocol also requires that the production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

> '*(i) All economically feasible steps have been taken to* ***minimise the essential use*** *and any associated* ***emission*** *of the controlled substance; and*
>
> *(ii) The controlled substance is not available in sufficient quantity and quality from* ***existing stocks of banked or recycled controlled substances****, also bearing in mind the developing countries' need for controlled substances'*

It is important to recall that the Montreal Protocol (implemented in the EU by the Ozone Depleting Substances (ODS) Regulation[27]) is one of the few existing examples of where the essential use concept is used to exempt uses of certain chemicals from restrictions. It is focused on a group of chemicals with broad international consensus on the need for stringent action to remove their use and release. Other pieces of legislation refer to 'essential' uses, but in other contexts, for example, without reference to necessity for health or safety, functioning of society, and absence of alternatives[28].

The CSS acknowledges that the scope covered by the EU chemicals regulatory framework is much broader than the specific scope of chemicals covered by the Montreal Protocol. In addition, a

[26] United Nations Environmental Programme, UNEP. The Montreal Protocol on Substances that Deplete the Ozone Layer, Decision IV/25: Essential uses. Retrieved 2022-11-22 at: https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses#:~:text=the%20Ozone%20Layer-,The%20Montreal%20Protocol%20on%20Substances%20that%20Deplete%20the%20Ozone%20Layer,consumption%20of%20ozone%2Ddepleting%20substances.

[27] Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

[28] The Biocidal Products Regulation Article 5(2)(b) allows for the approval of active substances that could be otherwise not approved in accordance with Article 5(1) if evidence is available to show that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment.

CARACAL paper[29] noted that the scope of uses considered under REACH and related chemicals legislation is much more diverse and far-reaching, and therefore, it would be more difficult to pre-define what is an essential or non-essential use for society under REACH and related chemicals legislation compared to the Montreal Protocol.

The CSS recommends that the criteria should be properly defined to ensure coherent application across EU legislation and should take into consideration the needs for achieving the green and digital transition. The CSS suggests that the criteria should guide the application of the concept in all relevant EU legislation for both generic and specific risk assessments.

In this context and to bring further definition of what the essential use concept means, this chapter discusses elements to guide the application of the essential use concept, as well as further descriptions of the criteria, which could be used under REACH and other legislation. Notably, Task 2 (information gathering and analysis) demonstrated that the application of the essential use concept (or similar) in other pieces of legislation has generally not been accompanied by detailed criteria/definitions. Thus, this exercise (elaborating on criteria) is already going one step further, to reduce subjectivity.

3.2 Elements to guide the application of the essential use concept

The following section outlines elements which set the **scope** to help guide the application of the essential use concept and is organised by: 1. Substances under scope; 2. Regulatory approaches under scope; 3. Sectors under scope; 4. Scope of 'use' and 'function'; 5. Time scope. For each element, the 'starting point', e.g. as set out by the CSS and the Terms of Reference for the project, is described, followed by a summary of supporting evidence on the topic obtained through consultation and desk-based research, and finally, the conclusions from the project team for each element.

3.2.1 Substances under scope

Starting point

The essential use concept is **not a tool to apply to all chemicals**; instead, it should only apply to the uses of the **most harmful chemicals** which are a priority for phasing out, in particular, in consumer products. Most harmful chemicals are referred to in the CSS as chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bio-accumulative, as well as chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ[30]. The CSS aims to phase out these substances for all non-essential uses because of the level of concern raised by their hazard properties and potential human and environmental exposure.

The essential use concept is **not** a tool to discern whether chemicals themselves are essential or non-essential for society, rather it will apply to specific **use(s)** of substances. Further information on this is presented under 'scope of use and function'.

[29] European Commission (2020). 37th Meeting of Competent Authorities for REACH and CLP (CARACAL), Concerns 'Essential Uses' Doc: CA/61/2020. 12 November 2020.
[30] As noted in the CARACAL document CA/19/2022, PMT and vPvM substances are not mentioned in the CSS among the hazard classes covered as most harmful chemicals. However, the CSS announces that they will be a new hazard category under the CLP Regulation and included among the hazard classes for which substances of very high concern (SVHC) may be identified.

Supporting evidence

Clarity on the substances under scope – Stakeholders (NGOs and business associations) requested that the scope for substances could be further clarified, for example by using the globally harmonised hazard classification system (GHS), and harmonising with criteria for identification of SVHCs (CMR category 1A or 1B, PBTs, vPvBs, or substances causing an equivalent level of concern). Notably, the CLP Regulation is currently undergoing revision (with upcoming adoption by the Commission)[31] which might see new hazard classes for endocrine disruptors, PBT, vPvM, and PMT substances. This could present an opportunity to further define the most harmful chemicals and bring coherency between legislation.

VVA (Unpublished)[32] targeted the most harmful chemicals in the study on the reform of REACH authorisation and restriction. Although not explicitly referred to as the most harmful chemicals, they refer to hazard classes which could be affected by the extension of the generic risk management approach (GRA)[33] (which is proposed for the most harmful chemicals). These hazard classes include endocrine disruption (for human health and the environment); persistent, bioaccumulative and toxic; very persistent very bioaccumulative; specific target organ toxicity (repeated exposure) (Cat. 1); specific target organ toxicity (single exposure) (Cat. 1); persistent, mobile and toxic; very persistent and very mobile; and carcinogenic, mutagenic, and toxic to reproduction.

Suggestions to narrow the scope of substances affected – There were comments from trade associations that the essential use concept could be applied to a smaller range of substances, given that both its historic use in the Montreal Protocol and its proposed use from academia[34] had much narrower scope for substance coverage (ozone-depleting substances and PFAS respectively). Concern generally stemmed from the unknown scale of potential impacts anticipated from a wide application of the concept.

A few stakeholders from industry suggested that some uses for most harmful chemicals should be derogated or authorised without needing to assess whether they meet the essential use criteria, for example, there were suggestions to retain REACH exemptions for scientific R&D and to exempt uses in the medical sector from requiring assessment. Sector coverage is discussed below.

A common suggestion from most industry respondents to narrow the scope of substances affected by the essential use concept was to only apply the concept where uses of substances cannot be shown to be 'safe'. Industry did not provide a definition of 'safe' use. Instead, in this context, it referred to uses of low quantities of substances, uses as intermediates, and uses where the substance is contained or consumed in a process.

[31] European Commission, (2021). Have your say – Revision of EU legislation on hazard classification, labelling and packaging of chemicals (public consultation). Retrieved 2022-11-22 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals_en.

[32] Valdani Vicari & Associati, VVA (Unpublished). 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. Third Draft Final Report [06/09/2022].

[33] The generic risk management approach (GRA) is currently applied for carcinogenic, mutagenic and reprotoxic (CMR) substances under REACH Article 68(2) and in certain product specific legislation, such as for toys and cosmetics. In REACH it empowers the Commission to propose restrictions for CMR substances in products and articles which could be used by consumers, while for toys and cosmetics the restriction is already built-in the legislation and is automatic (for toys) once a substance get a harmonised classification (in certain hazard categories) or semi-automatic (for cosmetic) where the substances with newly harmonised classifications need to be added to the list of banned substances under the Cosmetics Regulation. For substances under the scope of GRA, exposure potential for health and environment is considered generically and a risk can be assumed as default without the need for specific risk assessment (which considers exposure in detail). GRA is used to overcome limitations that for the most harmful chemicals often no safe exposure levels can be derived and the exposure during the whole life cycle (production, use, handling of waste and recycling) is very difficult to accurately estimate.

[34] Cousins, I.T.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Ng, C.A.; Patton, S.; Scheringer, M.; Trier, X.; Vierke, L.; Wang, Z.; DeWitt, J.C. (2019), The concept of essential use for determining when uses of PFASs can be phased out. *Environmental Science: Processes & Impacts, 21, 1803-1815.*

A summary of the input received from consultation on the 'safe' use argument is included in Appendix C. Overall, the decision on whether 'safe' uses could be exempt from the essential use concept is beyond the scope of this project and depends on the extent to which regulators decide to implement the essential use concept in legislation. For example, under REACH, the Commission is assessing whether exclusions from restrictions would be needed in certain exceptional cases on the basis of minimal exposure throughout the life cycle, in addition to essential uses.[35]

Conclusions – Substances under scope

The essential use concept should only apply to the **uses** of the **most harmful chemicals** which are a priority for phasing out. The most harmful chemicals are currently referred to in the CSS as those that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bio-accumulative, as well as chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ. Further definition to 'most harmful chemicals' could be sought by considering legally defined hazard classes, pending the revision of the CLP Regulation which is ongoing at the time of writing.

Substances under scope may vary by legislation, due to differences in existing legislation-specific provisions which allow exemptions from bans of substances based on criteria other than essentiality. For example, current REACH includes exemptions from authorisation for substances used as intermediates and in scientific research and development. The extent to which the essential use concept could be used to replace these criteria in various pieces of legislation is beyond the scope of this project.

3.2.2 Regulatory approaches under scope

Starting point

The essential use concept is intended to be a horizontal concept, therefore not specific to any one piece of legislation. The criteria should be properly defined to enable coherent application across all relevant EU legislation for both generic and specific risk assessments, as well as the extension of GRA for consumer and professional uses, for a progressive phase out of the most harmful chemicals, even though detailed implementation of the concept may vary.

Supporting evidence

As the central pillar of EU chemicals legislation (alongside CLP), implementation of the essential use concept is pertinent for REACH. REACH regulates thousands of chemicals with the goal to protect human health and the environment and is currently under revision, presenting an opportunity to improve the existing processes of authorisation and restriction through several measures including the introduction of the essential use concept. Most NGOs, public authorities, and academia stakeholders responding to the public consultation on the targeted revision of REACH[36] generally supported that implementation of the concept in REACH could help improve protection of the environment and human health. Most industry representatives disagreed that implementation of the concept in REACH could lead to these benefits.

[35] European Commission (2022). CA/45/2022, 45th Meeting of Competent Authorities for REACH and CLP (CARACAL).
[36] European Commission, (2022). Have your say - revision of REACH Regulation to help achieve a toxic-free environment (public consultation). Retrieved 2022-11-22 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/public-consultation_en.

A number of other pieces of EU legislation have also been identified where the application of the essential use concept could potentially be beneficial and therefore could be examined, for example, in the regulation of consumer products (e.g. cosmetics and food contact materials) as well as guiding a coherent application of criteria in the Taxonomy Regulation (and its delegated act) for sustainable investment (Regulation (EU) 2020/852).

Some stakeholders provided suggestions for which legislation should include the concept, for example, there was support for application to uses of chemicals in food contact materials, based on the concern that some current uses of the most harmful chemicals that are still allowed are not essential for society. Other pieces of legislation suggested for integration of the essential use concept include RoHS and the Toy Safety Directive.

The targeted survey to a wide spectrum of stakeholders highlighted a divide on whether the concept should apply to legislation other than REACH. The majority of NGOs, public authorities, and academia supported application of the essential use concept in other legislation. Business associations mostly showed resistance against this, while companies/businesses presented mixed views regarding implementation in other legislation. A significant proportion of respondents were uncertain.

Potential application of the essential use concept in legislation other than REACH is discussed in more detail in Section 5.2 (Figure 5.1 and Figure 5.2).

Conclusions – Regulatory approaches under scope

The essential use concept is horizontal and therefore could apply to all relevant EU legislation. The essential use concept would be anticipated to apply to all **restrictions of the most harmful chemicals**, be it in conjunction with the generic risk management approach (GRA) or with specific risk management approach (SRA).

Under **REACH**, the essential use concept could be relevant to assess requests for **derogations from restrictions** and **for authorisations**. Both the restriction and authorisation process are subject to potential changes under the revision of REACH. This is further explored in Part C (section 10) of this report on policy options.

Under current REACH, GRA is used to restrict carcinogenic, mutagenic or reprotoxic substances in uses by consumers under Article 68(2) and the revision is looking into extending these provisions to further hazard classes and to professional uses. Therefore, the essential use concept could be applied to assess whether derogations for the use of these substances from GRA restrictions could be allowed. Policy options for extending GRA are being investigated in a parallel study (VVA, Unpublished), which may shed light on how the two approaches (GRA and the essential use concept) could be applied in harmony.

Article 68(1) guides the restrictions for substances where there is unacceptable risk to human health or the environment. Currently, derogations excluding certain uses from restrictions may be granted, for example, if there are no alternatives or if alternatives pose greater risks, taking socio-economic aspects into account.[37] The essential use concept could be applied to justify derogations from restrictions or to limit the scope of restrictions of substances meeting the conditions for 'most harmful chemicals' for all uses (and for groups of substances).

In addition, the essential use concept could be applicable to granting authorisations under REACH. Notably, this depends on the outcome of the reform of authorisations and restrictions, for example, if the authorisation title is removed from REACH as per some of the policy options for the revision of REACH, this will not be applicable. Part C (section 10) of this report further

[37] Examples of reasons for derogations are listed in the ECHA (2007) guidance document for the preparation of an Annex XV dossier restriction.

explores how the essential use concept could apply to authorisation (e.g. how it would interact with, or replace, the socio-economic route for authorisation).

Regulatory processes under other EU legislation may also adopt the essential use concept for authorisations or derogations from restrictions based on both generic and specific risk assessments. Legislation other than REACH that may use the essential use concept remains to be determined and would be subject to individual impact assessment for each piece of legislation. Note that the possible introduction of an essential use concept has already been mentioned in several inception impact assessments, e.g. for the Cosmetic Products Regulation and Food Contact Materials Regulation. Further information on other pieces of legislation which may adopt the concept is provided under section 5.

3.2.3 Sectors under scope

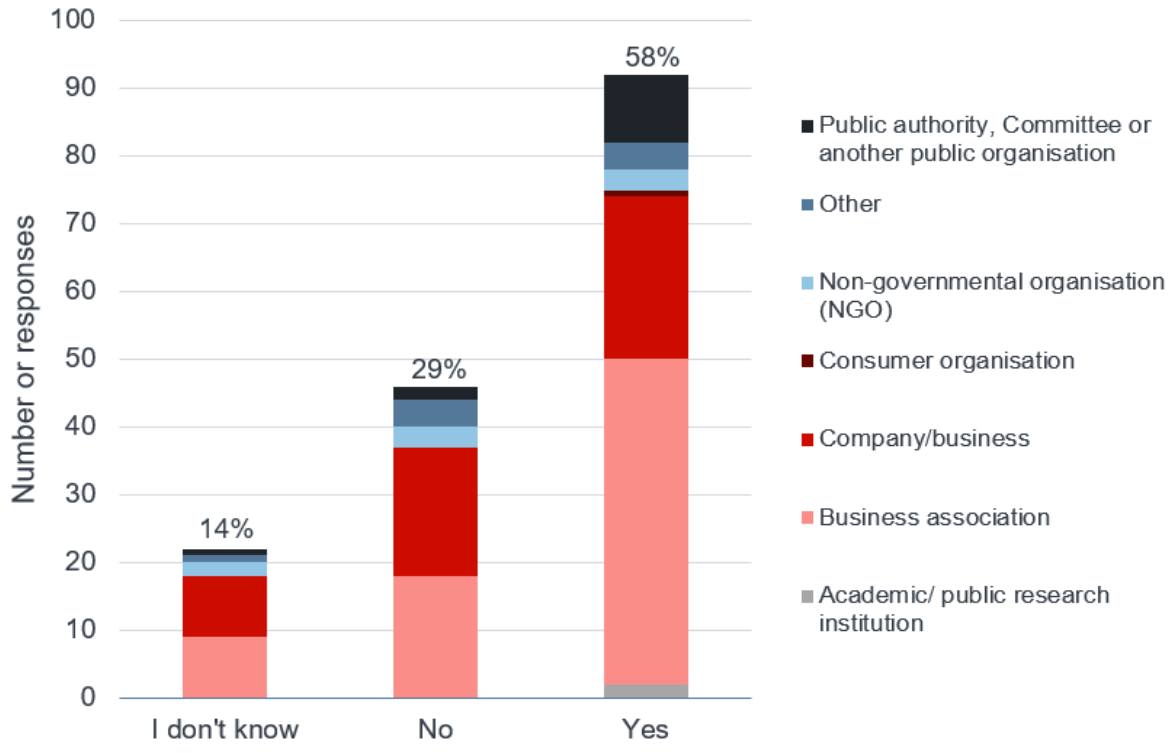
Starting point

The essential use concept is intended to be horizontal and not discriminate between specific sectors.

Supporting evidence

There were diverging stakeholder views on whether to differentiate application of the concept between sectors, although a larger number of respondents to the targeted survey (58%) agreed that essentiality of a use should not be based on a list of sectors. On the contrary, 29% of stakeholders disagreed, while 14% did not know (Figure 3.1).

Figure 3.1 Targeted survey responses to the question 'A starting assumption is that the assessment of whether a use of one of the most harmful chemicals is essential should not be based on lists of sectors. Do you agree with this statement?' (n = 160)



Stakeholders argued that sectors are often extremely diverse and the essentiality of chemical uses in different products/processes within a sector is also likely to vary on a case-by-case basis.

Some alternative responses suggested to exclude entire sectors based on opinions that they are essential for society, e.g. the medical sector. However, there are several reasons that use of one of the most harmful chemicals in a so-called 'essential sector' may not be automatically essential for society. Firstly, safer alternatives for the use may be available. Therefore, if essentiality of these specific uses is not assessed, there may be reduced incentive to substitute the most harmful chemicals. There may also be products or articles which themselves are necessary for health, safety and/or critical for the functioning of society, but the use of one of the most harmful chemicals in them is not (e.g. use of a chemical as a colourant may fall under this category in some products) if the chemical does not impact the necessity for health/safety or criticality for the functioning of society of the product or article. Furthermore, uses of most harmful chemicals may not qualify as necessary for health/safety if they relate to minor health benefits (in contrast to severe health problems) (noting that the question of what is 'necessary' is contentious among stakeholders).

Similarly, there were suggestions from two NGO position papers to label entire sectors as 'non-essential' for society because the use of one of the most harmful chemicals should never be needed, including for the following sectors: toys, textiles; furniture; clothes, apparel and shoes; food contact materials; personal care; cosmetics; luxury; leisure; decorative articles/purposes; sport products; and home maintenance and gardening. This argument has similar shortfalls in that it changes the frame from assessing the use to assessing the product / sector. For example, if food contact materials were labelled as non-essential for society, this could have negative consequences for food supplies which are necessary to maintain human health (e.g. to avoid malnutrition and related serious illness and death). As another example, in the textiles sector, use of a substance in personal protective equipment may be necessary for health and safety. Identifying uses that are necessary for health, safety, and/or critical for the functioning of society, and are without alternatives, therefore requires consideration of individual uses rather than broad consideration of entire sectors.

Conclusions – Sectors under scope

The essential use concept is intended to be horizontal and might apply to any sector. Specific uses within any sector could be essential or non-essential for society. Therefore, assessing the essentiality of sectors is not relevant to the essential use concept which is more appropriate to assess specific uses of most harmful chemicals regardless of sector. This is an important distinction given that applying the concept in a sweeping fashion could have negative consequences, e.g. allowing all uses in an 'essential sector' could allow uses of the most harmful chemicals which are not critical for the functioning of society / necessary for health/safety and/or substitutable. In addition, prohibiting all uses in 'non-essential sectors' could result in significant market disruption as well as withdrawal of uses which are necessary for health and/or safety.

The sectors where the essential use concept could apply depends on whether certain pieces of legislation adopt the concept, therefore, subject to the application of the concept under different regulatory remits, uses of the most harmful chemicals in all sectors by different actors along the supply chain (e.g. manufacturers, formulators, article producers and professional/industrial end-users of substances and mixtures) could be under the scope of the horizontal criteria.

3.2.4 Scope of 'use' and 'function'

Starting point

The essential use concept should apply to the **use** of a substance.

Use is defined under REACH Article 3 as any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. 'Identified use' is defined as a use of a substance on its own or in a mixture, or a use of a mixture, which is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.

Few pieces of EU legislation regulating chemicals (other than REACH) contain an explicit definition of 'use', hence there could be differences in interpretation for what this means under different pieces of legislation.

Under Regulation (EC) No 1005/2009 on substances that deplete the ozone layer (implementation the provision for the Montreal Protocol) the term 'use' is defined as "the utilisation of controlled substances or new substances in the production, maintenance or servicing, including refilling, of products and equipment or in other processes". While under the Cosmetic Products Regulation there is not an explicit definition of 'use', it is noted that the Annexes of the regulation, specifying details about the restrictions or derogations applied to named chemical substances, includes details related to their use, including product type, body parts, maximum concentration in ready for use mixture and guidance on age/vulnerable users.

The below section explores what information about a use should be provided in order to discern whether the use is essential to society. This has been raised as important by the Commission and stakeholders, for example, in terms of chemical function and end use.

Supporting evidence

Feedback from stakeholders and discussions with the Commission have highlighted uncertainty and differences in opinion on what information about a 'use' must be provided to discern whether it is essential for society, e.g. whether the substance function and/or service delivered by the final product within which the chemical is contained should be assessed.

Information explaining how to describe a use is provided in existing ECHA guidance documents. For example, the guidance on how to develop use descriptions in applications for authorisation[38] is most pertinent as it advises in detail how to describe a use as part of an application, contributing to the reasoning and justification for why an authorisation should be granted.

The so-called 'use-applied-for' is described by several elements including **substance function** (e.g. processing aid, extraction solvent, degreasing agent, corrosion inhibitor, swelling-agent, photo-sensitiser, pigment, mordant, surfactant); **product/s** resulting from the use of the Annex XIV substance and placed on the market; **technical requirements** (specifications or level of performance which must be met by products associated with the use, e.g. purity, hardness, resistance to corrosion, which may be defined by internationally recognised standards); and **industry sector** (e.g. chemical sector, pharmaceutical, mining, textile, aviation and aerospace).

The term 'use' is understood slightly differently in the context of REACH registration, based on the 'use descriptor' system. [39] Under the 'use descriptor' system, technical function (analogous to 'substance function' listed above) is described as the role that the substance fulfils when it is used.

[38] European Chemicals Agency, ECHA (2017). How to develop use descriptions in applications for authorisations. ECHA-17-H-07-EN. June 2017.
[39] European Chemicals Agency, ECHA (2015). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description. ECHA-15-G-11-EN. December 2015.

Other categories include sector of use, product category, process category, article category, and life cycle stage. However, as noted above, in terms of definition in the legal text, there is the single definition of "use" under Article 3. Notably, RPA is (at the time of writing) undertaking a technical support study on use and exposure information requirements for REACH registration, which could result in changes in how information on use is provided. For example, the policy options under the study include new requirements for downstream users to regularly report use and exposure information to the authorities and new requirements for registrants and downstream users to provide information prior to potential regulatory action.[40]

'Substance function' and 'technical function' (applied nearly synonymously within the above references) have been highlighted as important components by the Commission and by stakeholders. In some cases, essentiality (or non-essentiality) of the use for society may be clear from assessing the function alone, for example, uses with the technical function 'pigment', would be likely classified as non-essential as alternatives (safe pigments) are available.

However, stakeholders shared a common view that in many cases, technical function alone is insufficient to determine essentiality of a use for society, and that it should be framed in the context of the product type. For example, the function as a 'degreasing agent' may be necessary for health and safety in some products but not others. An example from the Montreal Protocol was highlighted, where derogations were made for CFCs in metred-dose inhalers based on the essentiality of the service provided by the product (treating asthma) not only the technical function (as a propellant gas).

ECHA guidance on use descriptions in applications for authorisation notes that 'product/s' may include products containing the Annex XIV substance as well as products produced using the substance which do not contain the substance themselves – therefore, the use description focuses on product/s even when the chemical is used in a process. Products may also be described at different levels of the supply/value chain; product(s) in the beginning (e.g. individual articles used in 'parts' of a product); product(s) in the middle (complex products made of multiple articles/parts assembled together but not yet functional as the final product); and 'final products' (e.g. products put on the market and used by professionals or consumers, which may be complex products).

For the analysis of alternatives, Tickner et al. (2015) suggest that three levels of 'function' should be described in order to facilitate substitution. These include chemical function (reflecting technical function of the substance), end-use function (function provided by the material/article/process), and function as service (function provided by the system, e.g. purpose of the final product or the process).[41] While not directly analogous to the 'use' of the substance, the 'service level' may be particularly relevant to define what the use means for society in terms of necessity for health, safety or criticality for the functioning of society, and regarding availability of alternatives. For example, bisphenol A may be used in thermal paper as a dye or colour developer (technical function). It is only when considering the 'function as service' (providing a record of sale to a consumer) that the scope for type of alternatives to be identified can be fully understood, for example, product alternatives could be considered, not only alternatives to the technical function which are usually limited to drop-in chemical replacements.

Cousins et al. (2021) refer to these three levels of function in the context of the essential use concept, stating that a use should only be considered essential for society if it is needed on all three levels.[42]

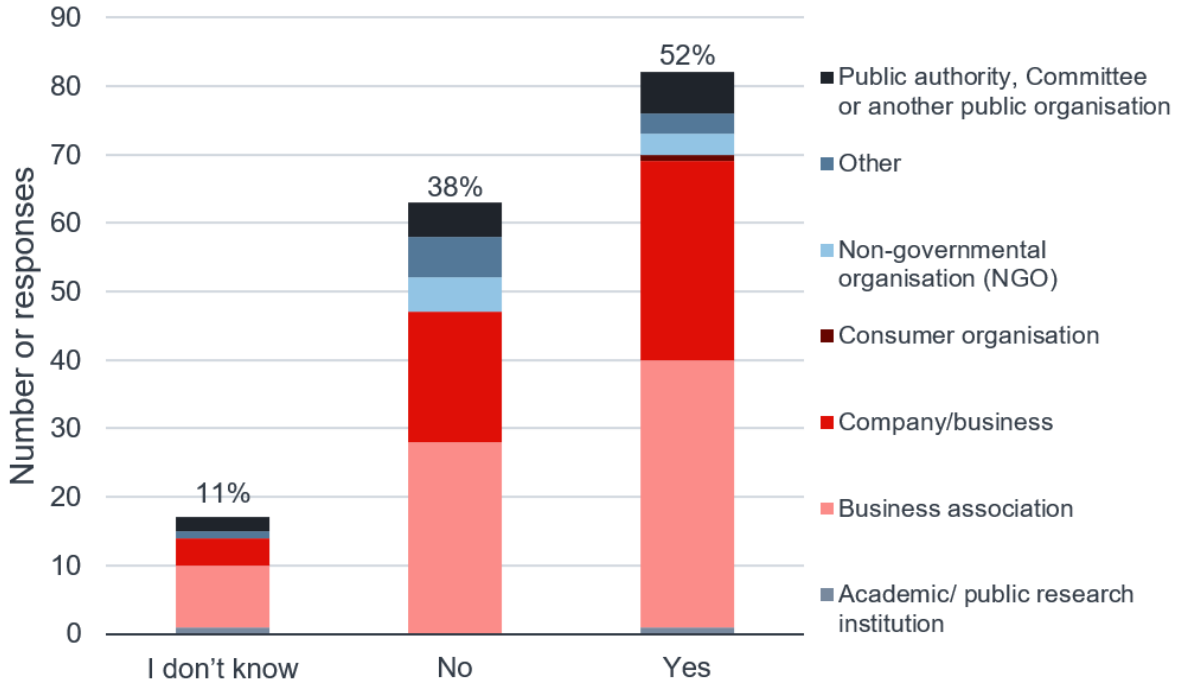
[40] Risk and Policy Analysts, RPA (Unpublished). Support to the Possible Introduction of Additional Information Requirements on Uses and Exposure in REACH

[41] Tickner, J.A.; Schifano, J.N.; Blake, A.; Rudisill, C.; Mulvihill, M.J. (2015), Advancing Safer Alternatives Through Functional Substitution. *Environmental Science & Technology, 49, 742-749.*

[42] Cousins, I.T.; DeWitt, J.C.; Glüge, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Ng, C.A.; Patton, S.; Scheringer, M.; Trier, X.; Wang, Z.; (2021), Finding essentiality feasible: common questions and misinterpretations concerning the "essential-use" concept. *Environmental Science: Processes & Impacts, 23, 1079-1087.*

The topic of what should be assessed under the essential use concept was further explored in the targeted survey, where stakeholders were asked whether they agreed that use of the most harmful chemical in a product, rather than the product/article/mixture/process/service itself, should be assessed for its essentiality for society. The quantitative findings are displayed below, showing a divide between stakeholders as 50% respondents agreed, 40% disagreed, and 10% did not know (Figure 3.2).

Figure 3.2 Targeted survey responses to the question 'Do you agree that the essentiality of the use of the most harmful chemical in a product/article/mixture should be assessed, not whether a product/article/mixture/process/service is in itself essential or not?' (n = 162)



Qualitative elaboration by stakeholders revealed a range of opinions on assessing use and assessing products under the essential use concept. The most prevalent opinion among all types of stakeholders (identified from the survey as well as position papers and interviews) was that use and product are interlinked and cannot be separated / assessed as two different aspects.

Arguments for assessing use of the most harmful chemicals, rather than the products themselves, suggested that assessment of the product would be too subjective and complex, would go beyond the scope of the legislation, would risk discrimination of certain sectors, and would result in too many products being labelled non-essential for society which would be impractical to regulate. EU institutions supported the view that uses, rather than products, should be assessed. A hypothetical example was discussed of the use of one of the most harmful chemicals in a component of a roller coaster. The essential use concept should not in this case assess whether society needs roller coasters (the product), but whether one of the most harmful chemicals provides a technical function that would be needed for safety reasons in a component of the roller coaster, and therefore the use might be necessary for health/safety.

Approximately 15 of the stakeholders who selected 'yes' in the targeted survey (indicating support for assessment of use not product) for this question provided further elaboration which implied that they were not against assessment of the product, rather they thought that both use and product should be assessed (not one or the other). Of the stakeholders who answered 'no' for this question, most shared the view that both product and use should be assessed, noting that disregarding product would only allow partial consideration of societal needs. Some noted that

even though they were against the assessment of products, separation of the two concepts (use and product) would be difficult as an assessment of essentiality of a use would inevitably/automatically lead to an assessment of essentiality of the product.

Stakeholder inputs to consultation also highlighted that considering the **end** product in addition to technical function is particularly important for complex products made up of many parts. For example, a chemical might be used as a lubricant in a semiconductor which may be used as a component/part[43] in multiple end products. If technical function alone is considered, lubrication or photoresistance may not directly be necessary for health/safety or critical for the functioning of society, therefore might be deemed non-essential for society which would result in the withdrawal of these uses and subsequently the loss of the semiconductors if there are no available alternatives. This might have detrimental impacts to society, but only for some end products within which the semiconductor (component/part) is used. For example, if a medical device used to treat a severe health issue could not function properly without a semiconductor containing one of the most harmful chemicals, the use should be considered necessary for health and safety. If there are no alternatives which can perform the technical function (lubrication or photoresistance in the semi-conductor), in the end use (role of the semiconductor in the final medical device), or service (treatment of the severe health issue / role of the medical device), the use should be considered essential for society. Similarly, use in a semiconductor could be critical for the functioning of society if semiconductors containing most harmful chemicals are needed in electric cars to achieve reductions in greenhouse gas emission. On the other hand, the most harmful chemical may be used in semiconductors in toys for the same technical function, however, there are likely to be other toys not containing the most harmful chemicals, that children can also play with, therefore showing that alternatives are available (at the service level) and so the use would not be essential for society. This hypothetical scenario demonstrates that essential uses may only be realised when contextualising the technical function in terms of the specific end product, not only the technical function in a specific part of a product.

Consideration of the specific setting within which the end product is used may also be needed in addition to the considerations mentioned above. A hypothetical scenario was suggested where the use of a certain substance could be necessary for health in some settings if needed for lamps with a high colour rendering index (e.g. mercury has been exempted under RoHS for this use[44], but without mention of specific settings). For example, high colour rendering index lamps may be necessary for health in medical operating theatres to ensure exceptionally high visibility (if such visibility is required) so that surgeons can safely carry out operations to treat severe health issues. On the other hand, the same lamps may not be necessary for health in other settings (an example of shop floor lighting was provided by a stakeholder as a use that may not be necessary for health/safety).

While most stakeholders supported assessment of both the function and product to discern essentiality of a use for society, some suggested that the product alone should be assessed. There was support that assessment of the product would make the concept more operational, particularly for complex products (comprised of multiple parts). There were also opinions that if a product is not essential for society, there should be no need to assess the essentiality of the technical function. However, there are some cases for which assessment of the product alone would fail to identify essential uses. If the **technical function of a substance is not required for the proper functioning of a product**, e.g. product performance is not affected if you remove the substance from the formulation, then the use of the substance is clearly not essential for society because the process/product can adequately perform without the substance. For example, a substance used as a colourant (technical function) in a medical device (product) may not always provide added benefit

[43] In most, if not all, applications, semiconductors are “intermediate products”, rather than “end products”, as they are not used directly by professionals or consumers but fall within the middle of the supply/value chain and are further assembled into end products.

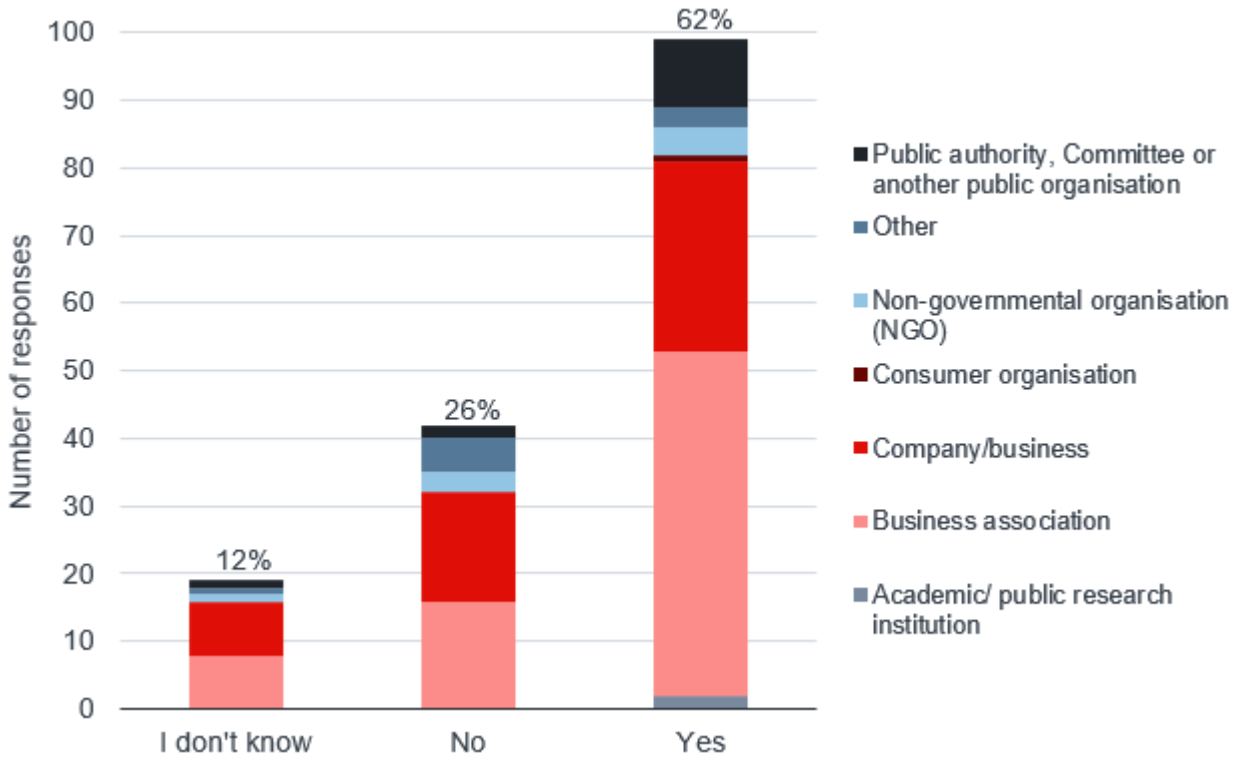
[44] Exemption 4(b), Annex III, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

to health/safety/criticality for the functioning of society, regardless of whether the process/product is critical for the functioning of society or necessary for health or safety.

Stakeholders showed disagreement on whether assessing products or uses is more efficient in terms of administrative burden and complexity.

Figure 3.3 highlights that 60% respondents agreed that essentiality assessments should not be based upon lists of products, asserting that even if product essentiality is assessed, this should not be based on a pre-defined list. Such a list would have to be broad and would be very difficult to create.

Figure 3.3 Targeted survey responses to the question 'A starting assumption is that the assessment of whether a use of one of the most harmful chemicals is essential should not be based on lists of products. Do you agree with this statement?' (n = 162)



Contrastingly, a couple of stakeholders (one NGO and one Member State agency) suggested (in a position paper and interview respectively) that there **should be** a list of **non-essential** products to facilitate the quick identification of non-essential uses, which may be easier to identify than essential uses.

Overall, the gathered evidence and views from stakeholders support the need to assess function and end product in the context of the wider societal need for the use in an end product within a defined setting, on a case-by-case basis, in order to critically appraise whether the use is necessary for health and/or safety or critical for the functioning of society.

Conclusions – Scope of 'use' and 'function'

This section was developed to help set the scope of 'use' and 'function' under the essential use concept, i.e., what aspects of a use should be considered to determine whether it is essential for society.

The definition of use under REACH could be used for the essential use concept, due to the lack of clear definition of use under other EU legislation. A 'use' is defined under REACH Article 3 as any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. 'Identified use' is defined as a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.

To discern whether a use is essential for society, sufficient information about the use should be provided to discern whether it is necessary for health/safety, critical for the functioning of society, and whether alternatives are available.

In order to allow the assessment of essentiality of a particular use, the following information is needed:

- the technical function provided by the substance (e.g. processing aid, extraction solvent, degreasing agent, and others recognised by the ECHA use descriptor system[45]);
- the need for the substance in the product/process (e.g. whether the product/process can deliver the service without the substance);
- the necessity of the technical function for the end use (e.g. final product) for health or safety, or the criticality of the technical function in the end-use for the functioning of society (further elaborated in section 3.3);
- whether the use of the most harmful chemical can be replaced by an alternative substance, material, product, process, or other technology (e.g. whether any alternative can sufficiently deliver the same service so that criticality for the functioning of society or necessity for health/safety is not compromised, note, this is further elaborated in section 3.3).

This information could facilitate an assessment in line with the step-wise approach shown in Figure 3.7, which highlights how the use should be assessed in terms of scoping, the assessment of criticality for the functioning of society and necessity for health/safety, the alternatives assessment, conditions for essential uses, and the review process.

Information on use could be provided qualitatively, however, the argument for claiming that a use is essential for society could be strengthened by quantitative data if available. Information on use should be described in a way that allows it to be understood in the context of wider societal needs rather than benefits to the applicant only. Information requirements to describe a use are expected to vary between pieces of legislation. The current use description guidance in REACH[46] could be used as a starting point for developing guidance in REACH and in other pieces of legislation.

Under REACH, **'technical function'** describes the role that the substance fulfils when it is used, i.e., what it does in a process, mixture, or article (as described by the use descriptor system under REACH registration, and synonymously to 'substance function' in 'the use applied for' under authorisation). For example, processing aid, extraction solvent, degreasing agent, corrosion inhibitor, etc. This could be used to describe the substance's function for the essential use concept, but to facilitate assessment of whether this is essential to society, it should be framed in the context of the end product within a defined setting on a case-by-case basis. Product descriptions are relevant for uses of substances where the substances are *incorporated in* the final product (or in a component/part of the final product) and for substances which are

[45] European Chemicals Agency, ECHA (2015). Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12 Use description. ECHA-15-G-11-EN. December 2015.
[46] European Chemicals Agency, ECHA (2017). How to develop use descriptions in applications for authorisation. ECHA-17-H-07-EN. June 2017.

used *to produce* the product but do not remain in the product itself. The description should cover the type of mixture or article in which the substance is contained.

3.2.5 Time scope

Starting point

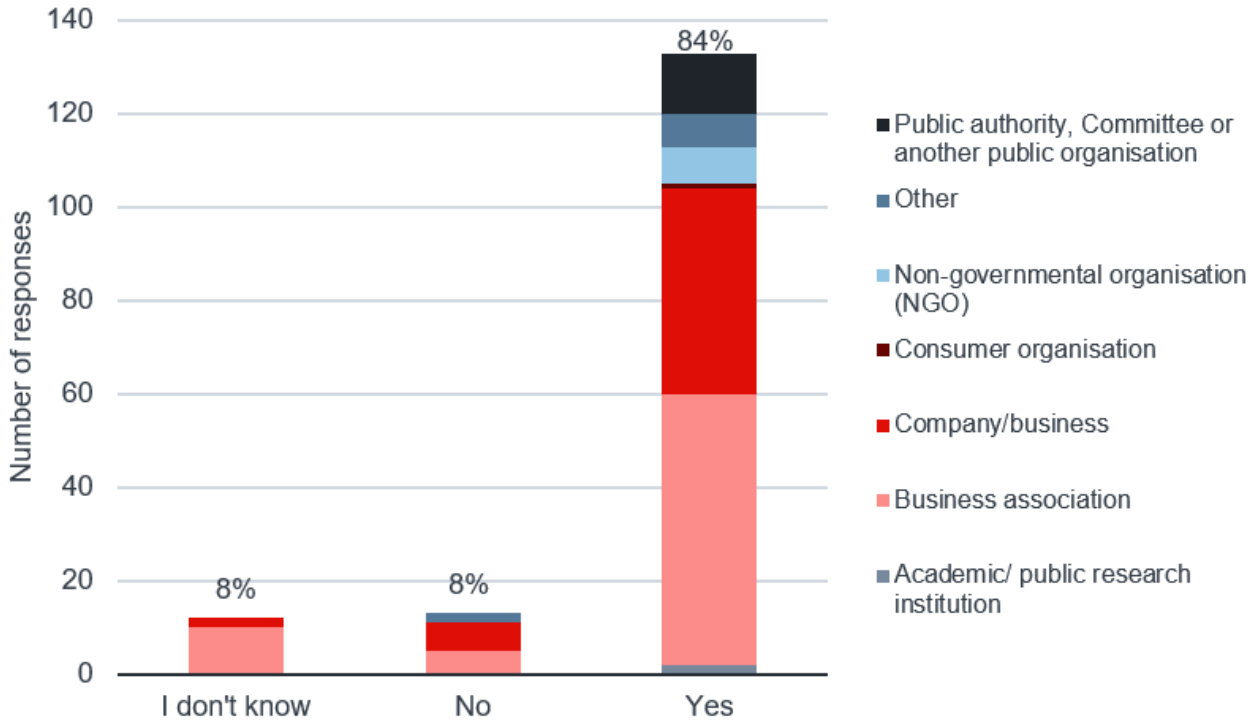
What is 'essential' for society evolves over time due to changing societal needs and technical progress. The derivation of the criteria and implementation of the concept must account for this fact.

Supporting evidence

Time scope for decisions on essential use – Stakeholders are in consensus that essentiality may change over time, and that it is not possible to fully predict what will be essential for society in the future. Several trade associations requested that the criteria should be regularly reassessed based on this limitation.

The majority of stakeholders support the view that uses assessed to be essential for society should be reviewed after a time period (Figure 3.4) in order to account for changing societal needs, technical developments, and to incentivise innovation and substitution of the most harmful chemicals.

Figure 3.4 Targeted survey responses to the question 'Do you agree that uses of substances considered as essential for society should be subject to reviews (i.e., any exemptions/authorisations should be limited in time)?' (n = 158)



Industry expressed that transitional periods for applicability of bans of uses should allow time for industry to respond, e.g. to identify, qualify, test, and validate suitable alternatives. This argument seems to be more relevant to the scope of GRA rather than the essential use concept, as it relates to bans rather than exemptions for bans, which are linked to the essential use concept.

Stakeholders mentioned that impermanence of decisions is important to allow flexibility to respond to emergencies. Industry emphasised that response to emergencies might be challenging for substances with uses deemed non-essential for society, as EU production capacity for the substance may decrease to a level which would not support higher production in case of emergency, and 'industrial inertia' may occur. Reversing decisions may have a delayed effect due to the process of returning production and manufacturing back to the EU. Part C (section 10.5.6) explores whether a fall-back mechanism for emergencies would be required within REACH but concludes that current provisions (e.g. Article 129 and Article 131) would already allow for actions to be taken by Member States and the Commission in case of any emergency or crisis. For other legislation, existing provisions for emergency response should be considered.

Some stakeholders suggested the decision review period should be set on a case-by-case basis due to differences between sectors and the complexity of products / difficulties in product redesign. For example, suggestions that essential uses for medical devices in the medical sector should be permanent where product development requires a long period of time (typically 10 – 15 years) and investments of millions of Euros. Others suggested that a case-by-case approach would be too burdensome as demonstrated by current REACH.

Specific periods of time for essential use decisions to be valid (before triggering a review) were suggested in the stakeholder feedback, e.g. 5 – 10 years, with one suggestion for a 20-year review period to reduce business uncertainty blocking investment. Similar to the case-by-case suggestion for length of review period, there was a suggestion to allow reviews at any time based on proposal by ECHA or a Member State.

Under Decision IV/25 of the Montreal Protocol, decisions on essentiality were time-limited but on a case-by-case basis. The duration of derogations varied, for example, emergency essential use of CFC-113 as a diluter for silicon grease during the manufacture of medical devices was derogated to cover the specific period 2010–2011 for the Dominican Republic, whereas other essential uses were permitted for longer time periods, e.g. use of CFCs in metred-dose inhalers for asthma and chronic obstructive pulmonary disease (phased out in 2016).

Conclusions – Time scope

Time scope for essential use criteria – Keeping criteria stable over time would facilitate their implementation, as this would bring greater predictability for all stakeholders using the concept and reduce the administrative burden which would be required if the criteria were frequently changed.

Given stakeholder concern that the definition of essentiality may change over time, it is preferable to keep the essential use criteria general enough that they are not limited in relevance to certain time periods. For example, it may not be appropriate to refer to the EU Green Deal or other political strategies in the criteria as policy objectives are typically impermanent.

Time scope for decisions on essential use – Implementation of the concept must address the changing nature of essentiality, as uses which are non-essential for society may become essential, and vice versa. For example, if one of the most harmful chemicals is essential for managing a risk to human health/safety at a certain time, it would become non-essential if the risk were eradicated.

Additionally, non-availability of alternatives may change due to technical progress in R&I and development of alternative substances or technologies. As such, decisions that uses are

essential for society should be reviewed after a time period to discern whether the use still qualifies as essential. Time periods should be established to define cut-off dates for new applications and end dates for existing applications.

For each essential use, the following considerations should be made to decide on the appropriate time period to allow the essential use before the decision is reviewed:

- The time period should be **short enough** so that:
  - Innovation and substitution of the use with safer alternatives is incentivised to ensure that suitable alternatives are available as soon as possible.
  - The use is not derogated/authorised for so long that it becomes non-essential for society within the time period and the use continues despite non-essentiality. It may be difficult to predict the length of time that the use will be critical for the functioning of society and/or necessary for health/safety. Predictions of the length of time for it to take for alternatives to be made available may be possible based on the substitution plan (described in the later section of this report on conditions after the essentiality decision (3.4.2)).
- The time period should be **long enough** so that:
  - There is sufficient time to switch to alternatives (depending on the case, they may need to be identified, tested, approved, and become available) (noting that between sectors and across product types, this can vary by a significant number of years). For example, if it is assessed that an alternative cannot be implemented for at least 10 years due to the time required for product redevelopment (a scenario which was suggested by some stakeholders), setting a significantly shorter review period would likely result in unnecessary administrative burden for both industry and regulators. Shorter review periods could also encourage less thorough testing of alternatives which could lead to regrettable substitution. These factors should be accounted for, based on information from the substitution plan.

These factors will vary on a case-by-case basis therefore the time period for which an essential use decision is valid should also vary accordingly.

If new information on alternatives, criticality for the functioning of society, or necessity for health/safety, is brought to light before the end of the time period, this should trigger an early review of the exemption for the essential use.

Importantly, the implementation of the concept should allow for quick response times in cases of emergency situations (e.g. COVID-19, spills, etc.). In REACH, it is thought that this would be facilitated by the existing Article 129 and 131 (see section 10.5.6). Provisions/requirements for emergencies may differ between different pieces of legislation which adopt the essential use concept.

3.3 Key findings for the definition of criteria

This section assesses the evidence gathered under the project and presents the key findings to further define criteria for the essential use concept. The criteria to conclude on essentiality of a use are described across four points: 1. Essentiality of a use for society; 2. Necessity for health and safety; 3. Criticality for the functioning of society; and 4. Lack of acceptable alternatives.

3.3.1 Essentiality of a use for society

Starting point

The criteria for a use of a substance to be defined as 'essential' for society (as per the CSS) require that the use is:

- necessary for health, safety **AND**/**OR** critical for the functioning of society
- **AND** there are no alternatives that are acceptable from the standpoint of environment and health.

Supporting evidence

Stakeholders are concerned about the subjectivity of the terms applied under the criteria, especially regarding 'functioning of society' which is not well-understood, and seemingly has minimal evidence of definition from existing legislation, including the Montreal Protocol, as well as in existing literature. Other concerns regarding terminology are on the scope for 'health' (stakeholders are divided on whether it should include well-being and mental health or only physical health) and whether the criterion on alternatives requires the alternatives to be feasible/available. The level of granularity of the criteria has been a point of discussion among stakeholders. There is a general consensus (particularly among trade associations as demonstrated in position papers) that such criteria alone (as stated in the CSS) are unlikely to achieve the objectives of the essential use concept in a predictable, effective, efficient and coherent way.

Stakeholders highlighted that subjectivity in criteria would lead to indefensibility of legal decisions on essentiality, as well as administrative burden due to disagreements and debates about what uses meet the criteria. Subjectivity and vagueness also present difficulties to stakeholders applying for uses of controlled substances (e.g. manufacturers and producers), as they may struggle to know how to demonstrate that a use is essential for society and may be faced with a higher degree of uncertainty on the outcome of the application. Clear criteria could improve the confidence of applicants applying for an authorisation or derogation from restriction based on essential use so that efforts are not wasted on applications for non-essential uses or in applying for authorisation/derogation from restriction without knowing how to demonstrate adherence to the criteria. Elaboration of the criteria is therefore considered critical for the functioning of society by stakeholders in order to bring predictability for different actors (from both the private and public sectors) and to ensure objectivity, and therefore robustness and defensibility of essentiality assessments.

At the same time, there has been some support (from trade associations) that too granular criteria (e.g. a checklist of criteria on 'what is essential for society') are not practical and may be too rigid to capture all essential uses. Stakeholders are also concerned that rigidity of criteria may prevent the criteria from accounting for the changing nature of essentiality over time, for example, if unprecedented essential uses are not captured by the criteria this could prevent essential responses to emergencies. In addition, some stakeholders (trade associations) argued that essentiality for society should be a political rather than scientific decision, and that criteria must be flexible to allow for political steer in decision making. Notably, the implementation of the concept under the Montreal Protocol relies on first a technical/scientific assessment and then a political decision making as nominations for essential uses are reviewed by committees (e.g. the Technical and Economic Assessment Panel and the Methyl Bromide Technical Options Committee) who provide recommendations which are taken into account in decision making during the Meeting of the Parties.

It is worth noting that transparency is considered key by stakeholders in the elaboration and application of the criteria.

Conclusions – Essentiality of a use for society

The arguments for and against different levels of detail/granularity/stringency/flexibility of the essential use criteria speak in favour of defining essentiality for society at multiple levels. We conclude that:

1. **The criteria** should be retained as included in the CSS.

The CSS criteria (i.e. necessary for health, safety or critical for the functioning of society AND there are no alternatives that are acceptable from the standpoint of environment and health) should be used.

The CSS criteria clearly communicate the intention of the concept in a simple way. The criteria are easy to interpret and general enough that they do not limit the concept to discriminate against products or sectors, or lead to inflexibility which could limit response to changing societal needs, including in emergency/crisis situations. Stakeholder concerns regarding terminology should be addressed by developing a clear understanding of the terminology. This is explored in the below sections on necessity for health/safety, criticality for the functioning of society, and acceptable alternatives.

As identified under Task 2, the essential use concept (or similar) has only been applied to a limited extent in existing/previous regulations, with limited elaboration of the meaning of essentiality for society. Similarly, although data gathering through Task 3 and consultation identified some suggestions for further criteria, these were often lacking in level of detail and justification. Changing the criteria (through additions of more detailed criteria or removal of any criteria) is therefore not recommended on the basis of the evidence reviewed. We propose instead that further definition of the essential use concept should be provided through horizontal and legislation-specific guidance, which can bring further meaning without the inflexibility implied by the term “criteria”.

2. **A horizontal guidance** should be used to bring further clarity and specificity in the application of the criteria across different pieces of legislation.

As the criteria on their own are unlikely to achieve the objectives in a predictable, effective, efficient and coherent way, a horizontal guidance document could provide more clarity, limit subjective interpretations and ambiguity in the implementation of the concept across legislation and increase coherence across different legislation. The guidance should strike a balance between flexibility and rigidity. In the following sections, we outline guidance elements to help define and understand what is meant by necessity for health and safety, criticality for the functioning of society, and lack of acceptable alternatives.

Such a horizontal guidance document (that could take into account the findings and analysis made in this report) could give definitions and examples of uses to help all actors involved in implementation of the essential use concept, in terms of applications for derogations from restrictions and authorisations, assessments of essentiality and decisions on essentiality. The guidance could help with predictability and efficiency, and therefore bring simplicity and reduced administrative burden. The detail in the guidance document could also support the objectiveness, robustness and defensibility of essential use decisions, while allowing room for political steer. The guidance document could help to avoid debates and disagreements on essentiality because of their granularity in comparison to the criteria. The main benefit of providing this level of detail in guidance rather than in the criteria is that it allows the criteria to retain flexibility (e.g. guidance may change over time and may allow for political steer), while still providing stakeholders with a level of detail which makes the criteria interpretable and implementable in a practical way.

The practical implementation based on the guidance document could be more sensitive than the criteria, for example, reflecting the context of what is essential for society at the time of decision-making, relating to societal needs, risks, and EU policy objectives.

3. **Legislation-specific guidance** should also be developed, as required, for pieces of legislation which adopt the essential use concept.

Due to differences between pieces of legislation (scope, purpose, and decision-making processes), there may be nuances in how the essential use concept is introduced across legislation. For example, in REACH, several options for how to implement the essential use concept have been considered, as described in Part C. Legislation-specific guidance could address these nuances. Guidance documents could be developed in a similar fashion to the current guidance documents provided by ECHA regarding REACH processes.

The below sections elaborate on the components of the essential use concept, which is summarised in section 3.5 in a stepwise approach (Figure 3.7).

3.3.2 Necessity for health and/or safety

Starting point

To meet this criterion, the use of the considered substance should be **necessary for health and/or safety**. Existing legislation with concepts similar to essential use have limited definitions of the scope and/or terms used in this criterion.

Supporting evidence

Health is defined by the WHO as a '**state of complete physical, mental and social well-being and not merely the absence of disease or infirmity**'.[47] At an EU level, there is no overarching definition of health and safety. In the context of worker safety, the EU Agency for the improvement of living and working conditions (Eurofound) share the WHO definition for health and note that health and safety goes beyond the avoidance of accidents and prevention of disease to include all aspects of a worker's well-being.[48] The International Labour Office (ILO) identifies occupational safety and health as "the discipline dealing with the prevention of work-related injuries and diseases as well as the protection and promotion of the health of workers"[49].

Stakeholders were divided on the scope for **health**, particularly on whether well-being and mental health should be included in the concept. Many industry representatives supported inclusion of mental health / well-being, indicating that exclusion could be seen as problematic. On the other hand, NGOs (including those advocating for human health protection) suggested that inclusion of mental health / well-being would make derogations or authorisations for uses too easy, and therefore limit the ability of the essential use concept to incentivise substitution. Some arguments suggested that a most harmful chemical will never be essential for mental health because there are likely to be other ways to achieve good mental health. However, in cases where/if this is true, uses would be more likely to be non-essential for society because "other ways to achieve good mental health" would show that alternatives exist, and therefore, the essential use concept would not justify derogations or authorisations. Overall, including mental health could be important if any uses of the most harmful

[47] World Health Organisation, WHO. Constitution of the World Health Organization. Retrieved 2022-11-22 at: https://www.who.int/about/governance/constitution.
[48] European Foundation for the Improvement of Living and Working Conditions, Eurofound (2015). European Observatory of Working Life: Health and safety. Retrieved 2022-11-22 at: https://www.eurofound.europa.eu/observatories/eurwork/industrial-relations-dictionary/health-and-safety#:~:text=Health%20and%20safety%20is%20given,of%20a%20worker's%20well%2Dbeing.
[49] International Labour Organisation (1998). Technical and ethical guidelines for workers' health surveillance.

chemicals could be required for specific treatment of a severe or life-threatening mental health issue where there are no alternatives.

An overarching definition for **safety** was not identified, however, no diverging views on the scope for safety were identified, and we consider that the concept is well recognised to cover the prevention and minimisation of risks which may cause harm to humans and to the environment. Safety for all citizens including workers and consumers is relevant, e.g. in terms of safety of consumer products[50], disaster risk management,[51] and in terms of both personal and public safety.

In the targeted survey, stakeholders were asked what the key factors are to assess if the use of one of the most harmful chemicals is necessary for health and/or safety. The most common responses included (with stakeholder type and number of responses): environmental health and safety (industry, public authorities, NGOs, n = 30); provision of (safe) food (industry, n = 19); use of the World Health Organisation definition of health (industry and 1 public authority, n = 17); mental health / well-being (industry, n = 17); provision of (safe and clean) water (industry, n = 12); unsafe products (industry, n = 8); health care provision (industry, n = 8); first responders and emergency services in the performance of their jobs (industry, n = 7); national security (industry, n = 7); public safety (industry, n = 7).

Common arguments from non-industry stakeholders (Member State competent authorities and a consultancy) included suggestions that necessity to health/safety should be a political decision. NGOs and public authorities suggested that the benefits to health/safety from use should outweigh the risks to health/safety over the chemical lifecycle. A respondent from academia suggested that the key question should be whether the use saves lives. Some respondents (a law firm and a public authority) suggested that product health and safety requirements should be considered.

Other, less common, suggestions for key factors to assess if a use of one of the most harmful chemicals is necessary for health/safety included: preventing disease; maintaining health; recovery of health; monitoring health and diagnosis; improving life quality; hygiene and cleaning (to prevent disease); nutrition; pollution control; medical devices; use in the manufacturing of necessary products; animal welfare; pest control; health impacts listed in tool #32 of the Better Regulation Toolbox[52]; personal and worker protection; environmental protection; road safety; safe packaging of food, beverages, medicines; safe transportation; safe use of machinery and industrial operations; fire protection; defence and military uses; security and policing.

Some stakeholders noted that defence is defined at a national level and therefore should not be addressed by the criteria. For REACH, substances may be exempted via national exemptions in the interest of defence, but not all Member States are applying this exemption for defence.

Environmental aspects (e.g. environmental health) were frequently suggested for inclusion in this criterion in the stakeholder survey. It is scientifically and politically well-recognised that human health and safety is dependent on certain environmental factors[53].

[50] European Commission, (2021). Consumer product safety: How product safety rules are defined and enforced in the EU, The General Product Safety Directive. Retrieved 2022-11-22 at: https://ec.europa.eu/info/business-economy-euro/product-safety-and-requirements/product-safety/consumer-product-safety_en.
[51] European Commission (2022). European Civil Protection and Humanitarian Aid Operations, European Disaster Risk Management Factsheet. Retrieved 2022-11-22 at: https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/european-disaster-risk-management_en.
[52] E.g., from section 3.2 of the toolbox: life expectancy; mortality; morbidity; health risks from substances or living organisms harmful to the natural environment; lifestyle-related determinants of health such as diet, physical activity etc; specific effects on particular risk groups of people; quality and/or access to health services and the financing and organisation of health systems; cross-border provision of services, referrals across-borders and cooperation in border regions; health risks to people/patients; effectiveness and sustainability of healthcare and long-term care services; access of certain populations to medicinal products and information, health or long-term care services.
[53] For example, the European Environment Agency, EEA (2019), highlight in the 2020 state and outlook of the environment that the global burden of disease caused by environmental pressures is three times greater than the cumulative burden from AIDS, tuberculosis and malaria.

An important consideration is the subjectivity of what is meant by 'necessary' for health/safety, i.e., to what extent health/safety depends on a use before the use qualifies as necessary. Stakeholder views ranged from suggestions that all beneficial uses related to health (e.g. well-being) should be included, whereas others referred to significant benefits, and others referred to uses which treat severe (not mild) health issues. Given the aim of the essential use concept, to phase out uses for all except those which are imperative for society, criteria which allowed all beneficial uses to be deemed as necessary for health/safety would likely be ineffective. One stakeholder suggested that necessity for health/safety should be quantifiably demonstrated in terms of reduced disease burden (e.g. quality-adjusted life years).

Another common suggestion from industry, instead of setting a hard threshold for what is necessary for health/safety, was to assess necessity on a case-by-case basis by weighing the benefits to health and safety against the risks. An NGO supported this argument, stating that necessity should be discerned if the positive effects to human health / safety outweigh the negative impacts of the chemical through its lifetime. It may be argued that this is contradictory to the underpinning purpose of the essential use concept (as risks are not relevant to whether the use is necessary for health/safety), however, it could be viewed as a more whole-rounded approach to consider what a use means to society. One company suggested this approach could be adopted in cases where essentiality for society is not clear.

Industry responses included another suggestion to help set a threshold for what is necessary for health/safety. This would assess essentiality for society by considering the potential impacts of a non-use scenario. That is, whether withdrawal of the use of the substance would have a detrimental impact on health and/or safety e.g. loss of life in contrast to an inconvenience. This frame might help to materialise the meaning of 'necessity for health and safety', particularly in difficult / more subjective cases.

The suggested perspective focusing on non-use may, however, change the narrative / conceptual meaning of the essential use concept which is intended to focus on essentiality of use not the negative impacts of non-use. Similar considerations are made under current REACH, for example, socio-economic analysis under authorisation considers impacts of non-use, but is limited in scope as the analysis typically focuses on impacts on the manufacturers/suppliers. In contrast, economic impacts to the manufacturer/supplier from the non-use are not relevant under the essential use concept, rather, analysis of non-use would be relevant if it focused only on elements of health and safety, not on other socio-economic considerations.

Stakeholders also suggested that the criteria should be flexible to allow for geographic differences, for example, the use of a substance in air conditioning might be necessary for health in southern Member States where high temperatures might otherwise cause negative health impacts, which are not relevant in northern Member States.

Conclusions – Necessity for health and/or safety

Defining what is truly 'necessary for health/safety' as clearly as possible can avoid subjectivity, indefensibility and impracticalities in applying for, assessing and deciding on uses necessary for health and/or safety. Horizontal guidance in Table 3.1 could reduce subjectivity in interpreting criteria while providing explanations and illustrations that are necessary for consistent interpretation of the criteria and allowing room for political steer, e.g. in cases where necessity for health/safety depends on societal needs which are difficult to predict.

When applying this criterion, emphasis must be placed on the word "necessary", meaning that uses which are only somewhat related to the health/safety criterion, e.g. uses which provide a low level of benefit or convenience, should not be deemed necessary for health/safety. Only uses upon which health and safety are dependent on should be considered as "necessary for health and/or safety". Consideration of the severity of potential impacts of withdrawal of uses on health and

safety (but not on other socio-economic considerations) may help to clarify this assessment but not in isolation.

The following table details possible elements that could be included in the horizontal guidance to define how to identify uses which are necessary for health and/or safety, based on inputs from the Commission, literature, and consultation of stakeholders.

Table 3.1 Elements to define the horizontal criterion for necessity for health and/or safety.

Elements	Description
The use of one of the most harmful chemicals is necessary for preventing, monitoring or treating severe health issues	Uses may include those in medical devices, pharmaceuticals, healthcare, or other health-related uses, directly linked to the **prevention, monitoring, or treatment of severe health issues.** Uses for prevention of health issues may extend beyond the health sector, for example, uses related to hygiene and cleaning or physical exercise. These uses should be directly linked to the prevention of human health risk factors which are linked to severe health issues, such as those identified by the Institute for Health Metrics and Evaluation / Risk Factors Collaborators under the Global Burden of Disease study (e.g. household air pollution, unsafe water, lead exposure).[54] The WHO definition for health (as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity) should be considered, keeping in mind the focus of the criterion on severe health issues. 'Severe' should be carefully interpreted to avoid subjectivity and ambiguity, and to ensure that only necessary (not only nice-to-have or beneficial) uses meet the criterion. No specific definition of 'severe health issue' was identified in the literature, therefore we recommend that the following are taken into account: • In the literature, several different terms are frequently used that could be viewed as analogous to 'severe health issues' in this context - including 'serious illness', 'advanced illness' and 'serious health condition'. Severe illness has been defined as any acute or chronic illness and/or health condition that carries a high risk of mortality, negatively impacts quality of life and daily function, and/or is burdensome in symptoms, treatments, or caregiver stress.[55] • The WHO highlights the severity of noncommunicable diseases such as cardiovascular diseases, cancers, respiratory diseases, and diabetes, which therefore would fall under scope.[56] • Severe health issues might be identified through considering the leading risk factors for health in Europe, however, efforts should also be made to capture health issues which are severe but less prevalent. • Public Health England uses the term severe mental illness to refer to people with psychological problems that are often so debilitating that

[54] The Lancet. Global Burden of Disease 2019 risk factor summaries. Retrieved 2022-11-23 at: https://www.thelancet.com/gbd/summaries.

[55] Radbruch, L.; De Lima, L.; Knaul, F.; Wenk, R.; Ali, Z.; Bhatnaghar, S.; Blanchard, C.; Bruera, E.; Buitrago, R.; Burla, C.; Callaway, M.; Munyoro, E.C.; Centeno, C.; Cleary, J.; Connor, S.; Davaasuren, O.; Downing, J.; Foley, K.; Goh, C.; Gomez-Garcia, W.; Harding, R.; Khan, Q.T.; Larkin, P.; Leng, M.; Luyirika, E.; Marston, J.; Moine, S.; Osman, H.; Pettus, K.; Puchalski, C.; Rajagopal, M.R.; Spence, D.; Spruijt, O.; Venkateswaran, C.; Wee, B.; Woodruff, R.; Yong, J.; Pastrana, T. (2020). Redefining Palliative Care — A New Consensus-Based Definition. *Journal of Pain and Symptom Management. 60, 754-764.*

[56] World Health Organization, WHO (2022). Noncommunicable diseases: Key facts. Retrieved 2022-11-22 at https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases.

Elements	Description
	their ability to engage in functional and occupational activities is severely impaired. For example, schizophrenia and bipolar disorder.[57] Further scoping of this element could be improved with advice from medical professionals, to bring better clarity on what can be defined as a severe health issue.
The use of one of the most harmful chemicals is necessary for sustaining basic conditions for human life and health	Basic needs for human life and health are recognised widely as **food, water, and shelter/security.** No specific EU or global definitions were identified, however, similar arguments were identified in the literature/online sources.[58] 'Basic' should be carefully interpreted to avoid sensitivities, subjectivity and ambiguity. The most relevant definitions from the literature included, for example: • For **food**, the FAO states that *food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life.*[59] • For **water**, the UN defines water security as *the capacity of a population to safeguard sustainable access to adequate quantities of and acceptable quality water for sustaining livelihoods, human well-being, and socio-economic development, for ensuring protection against water-borne pollution and water-related disasters, and for preserving ecosystems in a climate of peace and political stability.*[60] • For **shelter/security**, adequate housing was defined under the UN Global Shelter Strategy as *adequate privacy, adequate space, adequate security, adequate lighting and ventilation, adequate basic infrastructure and adequate location with regard to work and basic facilities-all at a reasonable cost.*[61]" Environmental health may be considered a basic condition for human life and health as certain environmental conditions are a prerequisite for good health.[62] An example of a necessary use could be one which is required to prevent air pollution, if it could be shown that human health impacts from the environmental risk were severe and there were no other ways to mitigate the risk.
The use of one of the most harmful chemicals is necessary for managing and preventing health	Health crises and emergencies could include: • Human health disease outbreaks • Emergencies anticipated to be addressed by ambulance services.

[57] Public Health England (2018). Severe mental illness (SMI) and physical health inequalities: briefing. Retrieved 2022-11-22 at: https://www.gov.uk/government/publications/severe-mental-illness-smi-physical-health-inequalities/severe-mental-illness-and-physical-health-inequalities-briefing#:~:text=The%20phrase%20severe%20mental%20illness,an%20SMI%20%5Bfootnote%201%5D.
[58] E.g., based on Maslow's Hierarchy of Needs, NASA, and recognised by Cousins et al. (2021) in the context of the essential use concept.
[59] Food and Agriculture Organization of the United Nations, FAO (2003). Trade reforms and food security, Chapter 2. Food security: concepts and measurement. Retrieved 2022-11-22 at: https://www.fao.org/3/y4671e/y4671e06.htm.
[60] International Institute for Sustainable Development, IISD (2013). UN-Water Brief Defines Water Security. Retrieved 2022-11-22 at: https://sdg.iisd.org/news/un-water-brief-defines-water-security/#:~:text=UN%2DWater%20proposes%20the%20following,against%20water%2Dborne%20pollution%20and.
[61] United Nations (1992). Global Strategy for Shelter to the Year 2000. Retrieved 2022-11-22 at: https://digitallibrary.un.org/record/136151?ln=en.
[62] World Health Organisation, WHO. Environmental health. Retrieved on 2022-11-24 at: https://www.who.int/health-topics/environmental-health#tab=tab_1; European Environment Agency, EEA. Glossary Environmental Health. Retrieved on 2022-11-24 at: https://www.eea.europa.eu/help/glossary/eea-glossary/environmental-health

Elements	Description
crises and emergencies	The above list is non-exhaustive because emergencies and health crises may not always be predictable, and so case-by-case justification of emergency/crisis situations may be required in some cases.
The use of one of the most harmful chemicals is necessary for personal safety	This includes uses of the most harmful chemicals needed for the proper functioning of products/processes where the purpose of the chemical/product/process is to ensure personal safety. For example: • uses required for the proper functioning of seatbelts; personal protective equipment for sports and the workplace; bulletproof vests; life jackets; fire alarms, etc. (as they all ensure personal safety). • uses ensuring fire resistance in products anticipated to be heated and uses ensuring lubrication in vehicle brakes. These types of uses could be justified based on technical requirements set by health and safety standards. To ensure that only necessary uses are included, this should not include uses where safety can be ensured by other means.
The use of one of the most harmful chemicals is necessary for public safety	Beyond personal safety, public safety should be covered by the essential use concept, for example, to include uses necessary for safety of public infrastructure (e.g. road safety, public building safety) as well uses required to ensure the effective functioning of emergency services to prevent danger to public safety (which could include, for example, military, police, anti-terrorism, cyber security, and fire safety services).
The use of one of the most harmful chemicals is necessary to address a danger to animal health which cannot be contained by other means	This element is refined from the Biocidal Products Regulation, which does not include definition for 'danger to animal health'. We suggest the following to be included in guidance: • Safeguarding animal health and welfare in line with EU standards.[63] • Prevention and control of diseases (including zoonoses) and parasites. • Prevention or minimisation of suffering caused to animals or pests, for example in the case of products used for pest control.

3.3.3 Criticality for the functioning of society

Starting point

The use of the considered substance should be **critical for the functioning of society**. Existing legislation with concepts similar to the essential use concept have limited definitions of the scope and/or criteria for such uses (as identified under Task 2).

Supporting evidence

Stakeholders noted the vagueness of the term 'critical for the functioning of society', demonstrating a need for improved understanding/definition. The concept has not been firmly defined in existing literature and legislation. Cousins et al. (2021) suggest that criticality for the functioning of society should be assessed based on judgement rather than an exhaustive or conclusive list of use

[63] European Food Safety Authority, EFSA (2022). Animal welfare. Retrieved 2022-11-22 at: https://www.efsa.europa.eu/en/topics/topic/animal-welfare.

categories.[64] Garnett and Van Calster (2021) also emphasise that such social considerations cannot easily be quantified or objectively assessed. [65] The inherent subjectivity of criticality for the functioning of society should be balanced with the desire from stakeholders for a clearer picture of what is meant by the term.

Notably, one NGO commented in a position paper that the distinction between 'criticality' (for the functioning of society) and 'necessity' (for health/safety) adds complexity and is not required. This might be the case as health and safety could be considered as critical to the functioning of society. Further, in stakeholder feedback there was significant overlap in the suggestions for both criteria (e.g. access to food and water, shelter, well-being, environmental health).

Suggestions for key factors required to assess if the use of one of the most harmful chemicals is critical for the functioning of society were received from stakeholders responding to the targeted survey and providing position papers. The most frequently mentioned topics were climate change prevention / decarbonisation, energy supply, sustainability, and cultural heritage aspects. Other suggestions included reference to: resource efficiency; environmental protection; circularity; communication; digitalisation; the Green Deal; transport; critical services (power, heat, housing); public services; competitiveness; policy objectives; durability (of products and one stakeholder referred to durability of infrastructure); access to clean and sufficient food and water; research and innovation; autonomy; critical infrastructure; well-being; education; consumer choice; e-mobility; employment; animal welfare; military uses; law and fundamental rights; social inequality; specific medical treatments (e.g. for immunocompromised patients).

A common suggestion from stakeholders was to include sustainability (e.g. with reference to the UN sustainable development goals, Green Deal objectives, or related aspects such as climate neutrality, circularity, environmental protection, and economic aspects of sustainability) within the criteria for what is critical for the functioning of society. One NGO responded to the survey suggesting that a use should be considered critical for the functioning of society if it contributes significantly to the sustainability of a critical process. However, it should be considered that the concept of sustainability is broad and therefore may not bring added value specifically as a criterion, although it is relevant to frame the narrative of the essential use concept.

Similar to the feedback on necessity for health/safety, there were suggestions to look at the impacts which would ensue in a non-use scenario in order to determine criticality for the functioning of society. Specifically, there were suggestions to consider the number of people who would be affected by withdrawal of a use, impacts on employment, impacts on products or services, and general impacts on society. A few stakeholders suggested to look at impacts on the economy, but most suggestions were to look at impacts on society. Most respondents suggested impacts should be severe for uses to be classified as critical for the functioning of society, e.g. unacceptable impacts / severe disruptions to society / critical consequences on society.

Many respondents to the survey (especially trade associations) suggested that there should not be a checklist to decide on criticality for the functioning of society, rather, it should be a political decision carried out on a case-by-case basis. There were also suggestions (e.g. from trade associations) to involve stakeholders in the assessment of what is critical for the functioning of society. This could be implemented in a similar way to the existing process for exemptions for active substances in biocidal products which are essential for the protection of cultural heritage. When Member States apply for derogations, the application is made public for a 60-day consultation to gather information which is then considered by the Commission when deciding

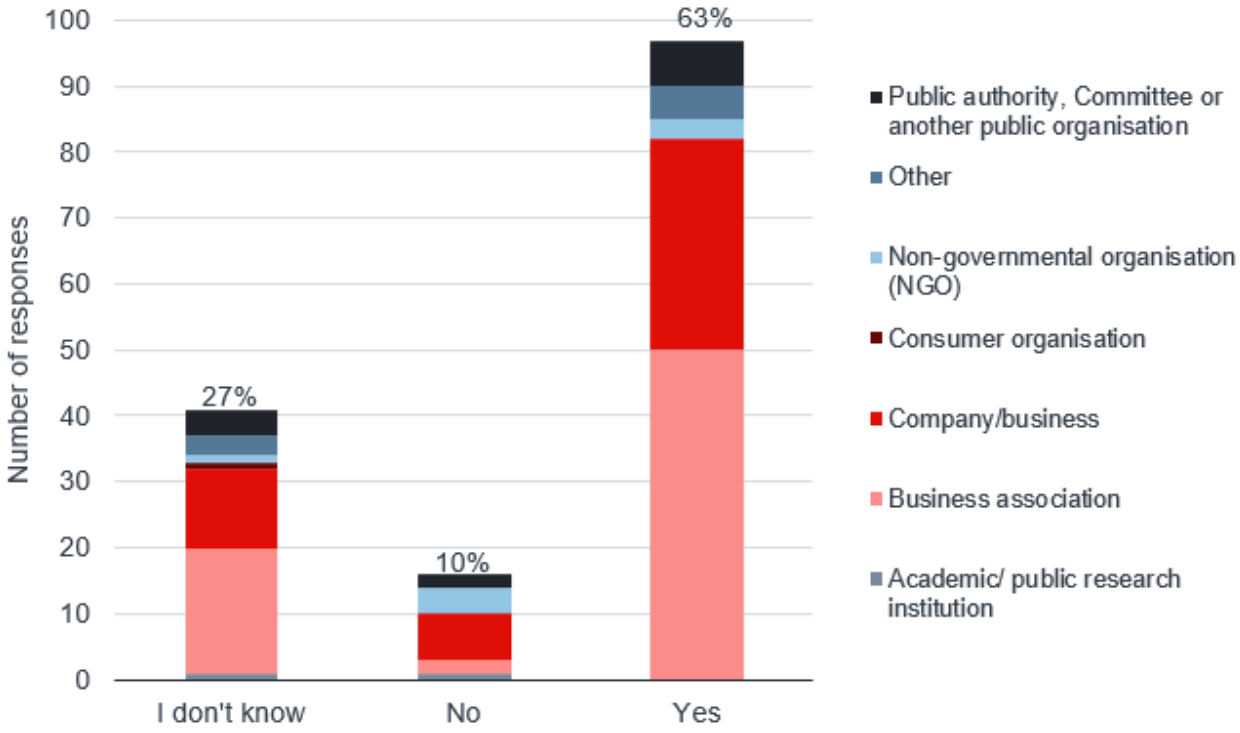
[64] Cousins, I.T.; DeWitt, J.C.; Glüge, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Ng, C.A.; Patton, S.; Scheringer, M.; Trier, X.; Wang, Z.; (2021), Finding essentiality feasible: common questions and misinterpretations concerning the "essential-use" concept. *Environmental Science: Processes & Impacts, 23, 1079-1087.*
[65] Garnett, K. and Van Calster, G. (2021). The Concept of Essential Use: A Novel Approach to Regulating Chemicals in the European Union. *Transnational Environmental Law, 10, 159-187.*

whether to allow Member States to grant authorisations for products for the use although the active substance is not approved.[66]

In general, there were comments not explicitly recommending criteria but recommending conditions that should be made when defining criteria, for example, suggestions to involve stakeholders, suggestions that the criteria should ensure that the benefits to society outweigh the costs associated with the use of the most harmful chemical, and suggestions that cultural differences should be taken into account.

Cultural heritage aspects – A key discussion point among stakeholders was how to take into account cultural heritage aspects. There are concerns that inclusion of cultural heritage aspects may be vague and subjective and hence allow uses to be authorised / derogated without valid justification. However, 60% of the stakeholders agreed that cultural heritage aspects should be considered in the assessment of criticality for the functioning of society (Figure 3-5). A larger proportion of all stakeholder types agreed rather than disagreed, except for NGOs who generally demonstrated a preference for excluding cultural heritage aspects.

Figure 3.5 Targeted survey responses to the question 'Should cultural heritage aspects be considered in the assessment on whether the use of one of the most harmful chemicals is critical for the functioning of society?' (n = 154)



Although most stakeholders supported consideration of these aspects, there were limited suggestions on how to refine the criteria to explicitly define what is critical for the functioning of society because of culture heritage. Definitions from existing legislation also appeared to be lacking (even in the Biocidal Products Regulation and Montreal Protocol where specific reference to cultural heritage is made).

Drawing on a reference from the UN[67], heritage is considered to be the cultural legacy we receive from the past. Cultural heritage includes (but is not limited to) monuments, collections of objects,

[66] European Chemicals Agency, ECHA. Consultation on derogations for the protection of cultural heritage. Retrieved 2022-11-22 at: https://echa.europa.eu/it/derogations-for-the-protection-of-cultural-heritage.
[67] United Nations Educational, Scientific and Cultural Organization, UNESCO. Cultural heritage. Retrieved 2022-11-23 at: https://en.unesco.org/fieldoffice/santiago/cultura/patrimonio.

oral traditions, performing arts, social manners, rituals, festive events, knowledge and practices related to nature and the universe, and knowledge and techniques linked to traditional crafts. Its value to society constitutes enrichment of cultural diversity, social capital, and creation of a sense of individual and collective belonging to maintain social and territorial cohesion.

Several stakeholders commented that cultural heritage should not be included in the criteria because its breadth and vagueness would prevent the essential use concept from being sufficiently targeted and limit its operability. Demonstrating, for example, that a use is critical for 'performing arts' or 'festive events' would not be an easy task.

The issue of subjectivity and vagueness may be resolved by requiring validation methods for uses which cannot objectively be assessed as critical for culture heritage because of the subjective and conceptual nature of these aspects. One suggestion from stakeholders was to conduct studies to identify the willingness to pay of EU citizens to prevent the loss of cultural heritage expected from the ban of the use of a substance. This would be burdensome but could be part of applications for essential use. Such a requirement would dissuade applicants from undertaking burdensome applications, enhancing the effectiveness of the concept as applications for non-essential uses would be discouraged, however, potential costs for society could arise as applications for essential uses would also be discouraged. Alternatively, or additionally, public consultations could be conducted to validate whether claims that use of a substance is critical to protect cultural heritage are justified.

Other views suggested that willingness to pay approaches can be of limited value because when deciding how much stakeholders are willing to pay for a use, they are unlikely to account for the risks from the use, for example, if these risks from chemicals are more likely to affect future generations rather than the stakeholders themselves.

Willingness to pay approaches may be limited in identifying criticality for the functioning of society because monetary value may not be relevant. For example, people are willing to pay more for luxury than for essential products.

We note that any assessment, through willingness to pay, stakeholder consultation, or other, must not only identify the general (e.g. average) importance of a use to society, but take into account the well-recognised fact that different groups of people have different needs, in terms of perception and value of cultural heritage, as well as the inherent nature of what is culturally important to them. Perception of cultural heritage varies based on geography, history, demography, and socioeconomic factors, and furthermore may only be directly relevant to a limited or defined group of society. Any assessment of these aspects should be sensitive to the needs of marginalised or minority groups whose views may be diluted by those from majority groups, e.g. in consultation activities. This may be challenging for scientific assessments. Alternative views from many stakeholders suggested that the criticality of the use of a substance for cultural heritage cannot be assessed by criteria, as it is a political issue with complexity and subjectivity that cannot be addressed scientifically. Some stakeholders suggested this aspect should be reviewed on a case-by-case basis if presented as a justification for criticality for the functioning of society.

Conclusions - Criticality for the functioning of society

Defining what is truly 'critical for the functioning of society' can avoid subjectivity, indefensibility, and impracticalities in applying for, assessing, and deciding on uses which are critical for the functioning of society. Horizontal guidance in Table 3.2 could reduce subjectivity in interpreting this criterion while providing explanations and illustrations that are necessary for consistent interpretation and allowing room for political steer, which will be particularly necessary for this criterion depending on societal needs which are difficult to predict.

When applying this criterion, emphasis must be placed on the word "critical", meaning that only uses upon which the functioning of society is dependent on should be deemed critical for the

functioning of society. Uses which are only somewhat related to the criterion, e.g. uses which provide a low level of benefit or convenience, should not be deemed critical for the functioning of society. Consideration of the severity of potential impacts of withdrawal of uses on the functioning of society (but not on other socio-economic considerations) may help to clarify this assessment, but not in isolation.

The following table details possible elements that could be included in the horizontal guidance to define how to identify uses which are critical for the functioning of society based on inputs from the Commission, literature, and consultation.

Table 3.2 Elements to define the criterion for criticality for the functioning of society.

Elements	Description
The use of one of the most harmful chemicals is critical to providing resources or services which are critical for society	Resources and services critical for society should be interpreted as those that must remain in service for society to function. Uses of the most harmful chemicals which could be critical to the functioning of society could include: • Uses required for the installation and maintenance of critical infrastructure. As per Directive 2008/114/EC, this infrastructure would include energy and transport. Other infrastructure could be argued to be critical, for example, the National Strategy for Critical Infrastructure Protection (KRITIS strategy) of Germany's Federal Office of Civil Protection and Disaster Assistance (BKK) defines critical infrastructures as follows: 'Critical infrastructures (CI) are organisational and physical structures and facilities of such vital importance to a nation's society and economy that their failure or degradation would result in sustained supply shortages, significant disruption of public safety and security, or other dramatic consequences.' • Uses required for the provision of other services critical for society, for example, waste treatment, water treatment, communication infrastructure, healthcare infrastructure. • Uses required to obtain or store critical raw materials as defined by the Commission.[68] Resources and services critical for society could be public or private but must be contextualised in terms of what they provide on a societal (rather than individual) level.
The use of one of the most harmful chemicals is critical to managing societal risks and impacts from natural and man-made crises and emergencies	While substances may be necessary to prevent/manage the immediate health and safety risks of emergencies (under the criterion for necessity for health/safety), there may also be substance uses which are critical for the functioning of society because they allow other societal risks and impacts from crisis/emergencies to be addressed. For example, repairing/preventing damage to infrastructure from natural disasters.
The use of one of the most harmful chemicals is	This element is recommended as is the case in the Montreal Protocol and the Biocidal Products Regulation. However, it is noted that no specific definition of 'cultural heritage' is provided under the Protocol nor in the Regulation.

[68] European Commission. Critical raw materials. Retrieved 2022-11-23 at: https://single-market-economy.ec.europa.eu/sectors/raw-materials/areas-specific-interest/critical-raw-materials_en.

Elements	Description
critical to protecting cultural heritage	Cultural and natural heritage is defined in the Operational Guidelines for the Implementation of the World Heritage Convention[69], with the following considered as "cultural heritage": (1) monuments: architectural works, works of monumental sculpture and painting, elements or structures of an archaeological nature, inscriptions, cave dwellings and combinations of features, which are of Outstanding Universal Value from the point of view of history, art or science; (2) groups of buildings: groups of separate or connected buildings which, because of their architecture, their homogeneity or their place in the landscape, are of Outstanding Universal Value from the point of view of history, art or science; (3) sites: works of man or the combined works of nature and of man, and areas including archaeological sites which are of Outstanding Universal Value from the historical, aesthetic, ethnological or anthropological points of view. Cultural heritage is critical to the functioning of society, but its scope is potentially very broad, meaning that proof of 'criticality' must be scrutinised to ensure that the essential use concept has the desired effect of limiting non-essential uses of the most harmful chemicals. For example, the focus on 'protection' of cultural heritage could be interpreted as a requirement to focus specifically on conservation rather than uses for aesthetics or decorative purposes not linked to tradition or history (e.g. luxury rather than critical purposes). In certain cases, aspects of decoration or aesthetic value can be recognised as having significant cultural value (e.g. listing as UNESCO World Heritage sites) and certain traditional world heritage practices recognised by UNESCO[70] could also be included in this element. Evidence of the potential loss of cultural diversity, social capital, collective belonging, and other services provided by cultural heritage if the use were assessed as non-critical for the functioning of society could help to evaluate this element. This element must be applied in a way that is sensitive to the differences between sociodemographic groups, ensuring that cultural heritage from all backgrounds is equally respected and assessed objectively in the same way. This will likely vary between Member States. As the least clear element (at the time of writing based on limited literature definitions and suggestions from stakeholders), assessment of this element may require more political judgement than some of the clearer elements.
The use of one of the most harmful chemicals is critical to running traditional and religious practices	This element is recommended as is the case in the Minamata Convention on Mercury. Similar caveats exist and considerations should be made as for the above element on cultural heritage.
The use of one of the most harmful chemicals is critical to protecting and restoring the	Environmental health is covered in the elements for necessity for health/safety, however, beyond health and safety, society is reliant upon the protection and restoration of the natural environment for ecosystem services and the functioning of society. In this context, uses may be critical:

[69] United Nations Educational, Scientific and Cultural Organization, UNESCO (2021). Operational guidelines for the implementation of the World Heritage Convention. Retrieved 2022-11-23 at: https://whc.unesco.org/en/guidelines/.
[70] UNESCO. Lists of Intangible Cultural Heritage and the Register of good safeguarding practices. Retrieved 2022-11-23 at: https://ich.unesco.org/en/lists.

Elements	Description
natural environment	• to reduce emissions of greenhouse gases or biodiversity loss (i.e., mitigation could not feasibly happen without these uses)[71] • for analysis and monitoring of pollutants. • for remediation of pollutants in the environment. The criticality of using the most harmful chemicals to address pollution for the functioning of society should be carefully considered because the use itself could contribute to pollution.

3.3.4 Lack of acceptable alternatives

Starting point

The essential use criteria require that there are **no alternatives that are acceptable from the standpoint of environment and health.**

The criterion is not elaborated in the CSS, for example, the term 'acceptable' is not defined. Under the Montreal Protocol, the essential use concept specified that alternatives should be available and technically and economically feasible.

Supporting evidence

<u>*Suitability of the alternative*</u> – Several stakeholders (business associations and NGOs) raised questions on whether alternatives would be required to be available / suitable / technically or economically feasible. There was concern that bans of substances could be unjustified if alternatives are not yet feasible (e.g. currently at research and development stage but not available on the market) or not available in sufficient quantities (e.g. if EU production capacity for the alternative is insufficient). Support to include these considerations is also seen in the literature, for example, Cousins et al. include reference to 'viable alternatives' under the essential use concept[72].

Under current REACH, authorisations may be granted in cases where analysis of alternatives shows that there are suitable alternatives in *general* but these alternatives are not *feasible* for the applicant or downstream users (this was clarified by the Commission after the EU General Court judgment of 7 March 2019 in Case T-837/16, prior to which, the question of general availability had not been considered[73]). For example, if certain individual companies cannot substitute with an alternative, but other companies can, authorisation for use could be granted under the current authorisation system if they have provided a credible substitution plan. Notably, the essential use concept is intended to focus on societal needs of allowing essential uses of substances, therefore the scope for feasibility requirements may differ. Under the current restriction title of REACH, feasibility for society as a whole is already accounted for, although there is less information on examination of alternatives under restriction guidance and Annex XVII in comparison to the guidance for authorisation.

[71] Proving criticality for the functioning of society should involve gathering substantial evidence of the extent to which the use could contribute to EU legislation and international treaties, for example the UN Paris Agreement on climate change and the EU biodiversity strategy for 2030.
[72] Glüge, J.; London, R.; Cousins, I.T.; DeWitt, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Ng, C.A., Patton, S.; Trier, X.; Wang, Z.; Scheringer, M. (2020). Information Requirements under the Essential-Use Concept: PFAS Case Studies. *Environmental Science & Technology, 56, 6232-6242.*
[73] European Commission (2020). Assessment of alternatives: Suitable alternative available in general & requirement for a substitution plan. 27 May 2020.

A 'suitable alternative' is defined under current REACH guidance (based on the judgement of case T-837/16 par. 72-76) as an alternative (to the controlled substance) '*for the use applied for, which is **safer** (i.e. entailing a lower risk for human health or the environment) and **technically and economically feasible** in the EU (i.e. not in abstract or in laboratory conditions or under conditions that are of exceptional nature). Furthermore, it must be **available** from the perspective of production capacities of alternative substances, or from the perspective of feasibility of the alternative technology, and in light of the legal and factual requirements for putting them into circulation'.* [74]

ECHA documents are already available to further scope what is meant by technical and economic feasibility and availability, for example, economic feasibility should cover net compliance costs, financial viability and the ability of different actors to pass costs down the supply chain, impacts on competitiveness.[75] NGOs in the survey (and interviews) supported the view that acceptable alternatives may be more costly, but feasibility in terms of economic practicality needs to be better defined under the essential use concept.

Another contributing factor to the 'suitability' of an alternative may be the level of technical performance it achieves, and whether a lower technical performance of an alternative in comparison to the most harmful chemical could be acceptable[76]. This has been an ongoing discussion in relation to the analysis of alternatives applied under REACH legislation and a case law relevant to this area exists. Under current REACH authorisation, technical requirements can be reflected in the use description and in the analysis of alternatives, including specifications or level of performance. This helps to identify alternative substances which can provide the same function, or alternative technologies, materials that can substitute the function.[77] Technical requirements can also help in assessing what actions are needed to make alternatives technically feasible.[78] For example, uses of chemicals in products with stringent technical requirements may take longer / be more difficult to substitute because of lengthier research, testing, industrialisation and requalification processes. According to the checklist for preparing an application for authorisation, applicants preparing authorisation applications should consider whether changing the product specification is possible[79].

In feedback from stakeholders from position papers, there was consensus that acceptability of loss of performance is a difficult discussion point. There were suggestions from NGOs and trade associations that performance requirements should be assessed on a case-by-case basis to determine for each use what loss of performance would be acceptable. One trade association suggested that loss of performance to some extent must be acceptable for practicality of the concept as substitution of substances in some products will inevitably result in loss of performance.

One NGO suggested that loss of performance associated with the alternative should be proven to be problematic before using it as grounds to justify that the alternative is not suitable, based on concern that current authorisation applications are not scrutinised enough to assess whether there are alternatives with a sufficient level of performance.

As referenced in section 3.2.4 on scope of 'use' and 'function', the frame for the analysis of alternatives posed by Tickner et al. (2015) would include alternatives at the service level. Notably, this could be interpreted as part of the current checklist for preparing an application for

[74] European Chemicals Agency, ECHA (2021). Guidance on the preparation of an application for authorisation. January 2021.
[75] European Chemicals Agency, ECHA (2007). Guidance for the preparation of an Annex XV dossier for restrictions. June 2007.
[76] It should be noted that the technical performance is part of the technical feasibility assessment not "suitability" under REACH.
[77] European Chemicals Agency, ECHA (2017). How to develop use descriptions in applications for authorisation. June 2017.
[78] European Chemicals Agency, ECHA (2021). Guidance on the preparation of an application for authorisation. January 2021.
[79] European Chemicals Agency, ECHA (2017). Checklist for preparing an application for authorisation or a review report. 12 May 2017.

authorisation which questions whether switching products has been considered.[80] An example provided by Tickner et al. is the use of bisphenol-A in thermal paper receipts, which could be substituted at the service-level by electronic receipts. Ultimately, the key consideration (as with loss of performance) is whether a change would compromise the purpose of the use in terms of health and/or safety, or the functioning of society.

Acceptability from a standpoint of human health and the environment - According to the CSS, alternatives must be **acceptable from the standpoint of health and the environment**. Acceptability is not defined but could be based on the existing definition for suitable alternative (described above) which requires that the alternative is safer (i.e., entailing an overall lower risk for human health and the environment in case the alternative would be used instead of the controlled substance). The current REACH guidance (assessment and comparison of overall risks[81] from alternatives and from the controlled substance, considered under the analysis of alternatives)[82], could therefore be a good starting point for the assessment of this acceptability. Building on this guidance was supported in general by workshop participants.

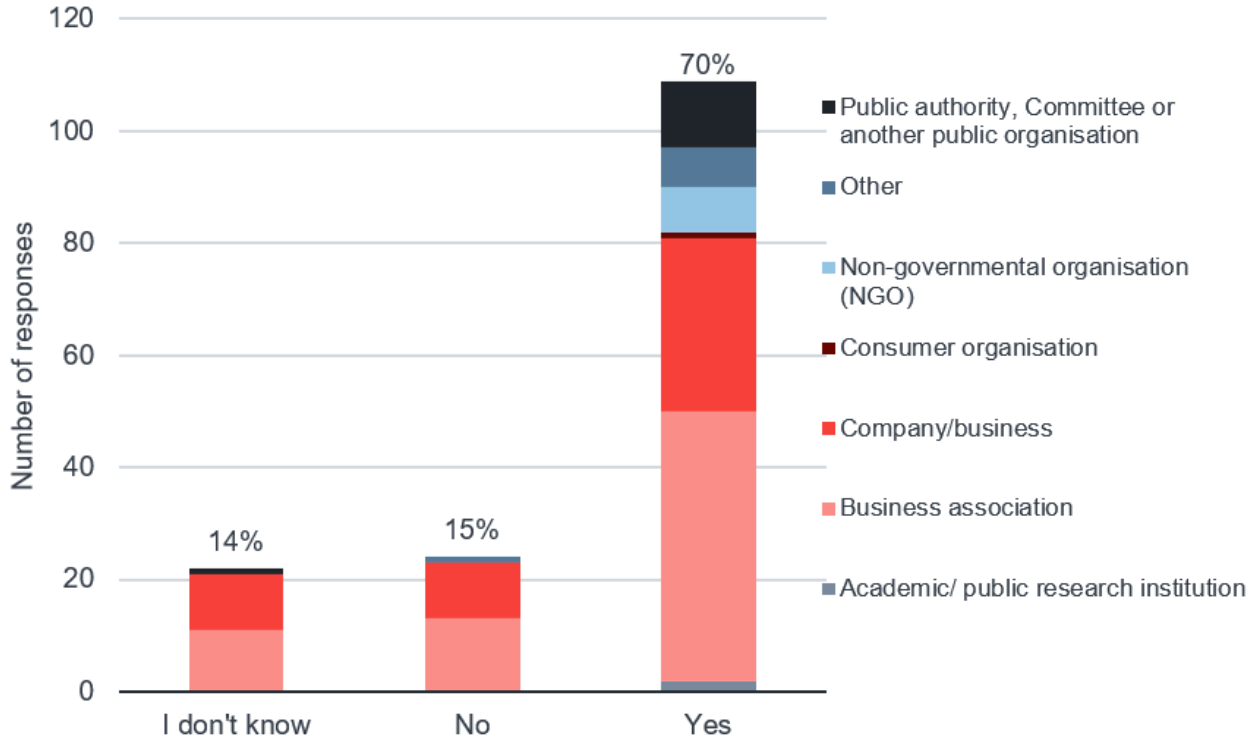
Industry associations suggested in position papers that alternatives should be assessed based on risks of the alternative from a lifecycle perspective. Some stakeholders suggested that in addition to risk, the overall sustainability of the alternatives should be considered (for example, if an alternative requires unsustainable material consumption or greenhouse gas emissions during manufacturing). Industry associations suggested that regrettable substitution could occur if overall sustainability is not taken into account. However, if all these aspects would need to be assessed for potential alternatives, they would also need to be assessed for the controlled substance in order to make the comparison of overall risks and wider sustainability possible. The burden of proof for this assessment would be on industry (in their authorisation/derogations requests).

One Member State suggested in an interview that acceptability should be determined through an impact assessment showing that the alternative is better for the environment than the controlled substance.

Information on alternatives – Figure 3.6 shows stakeholder responses to the essential use survey, highlighting that stakeholders would like also other actors than industry to provide information and evidence on alternatives.

[80] European Chemicals Agency, ECHA (2017). Checklist for preparing an application for authorisation or a review report. 12 May 2017.
[81] Overall risk refers to a combination of all hazards associated with a substance, not just those that distinguish the substance as 'most harmful'.
[82] European Chemicals Agency, ECHA (2021). Guidance on the preparation of an application for authorisation (europa.eu). January 2021.

Figure 3.6 Targeted survey responses to the question 'Should any actor (other than industry) provide information and evidence on alternatives?' (n = 155)



There were suggestions from stakeholders that any actor who has sufficient information on alternatives should provide information on the alternatives to ensure that all relevant information is taken into account. For example, academia might provide information, as Glüge et al. (2022) demonstrated PFAS alternatives availability through literature / patent searches. Although notably, they found limitations from the patent data as patents generally reflect an early stage of R&D and so do not describe readily available alternatives.[83]

Qualitatively, several NGOs elaborated (in the survey and in interviews) that contributions from non-industry stakeholders should be sought to critically assess and validate the information provided by industry. This stems from concern that currently applicants for authorisations (companies manufacturing/importing the substance) are not incentivised to identify alternatives. Suggestions for other stakeholders to get involved included downstream users and alternatives providers, as well as NGOs and researchers/scientists. Trade associations in interviews suggested that public and stakeholder consultation should be utilised and that a tendering process could be used as a contractual requirement for providing information and evidence on alternatives. A stakeholder from academia commented that the Commission should provide more guidance to help industry know how to substitute.

[83] Glüge, J.; London, R.; Cousins, I.T.; DeWitt, J.; Goldenman, G.; Herzke, D.; Lohmann, R.; Miller, M.; Ng, C.A., Patton, S.; Trier, X.; Wang, Z.; Scheringer, M. (2020). Information Requirements under the Essential-Use Concept: PFAS Case Studies. *Environmental Science & Technology, 56, 6232-6242.*

Key findings - Lack of alternatives acceptable from the standpoint of environment and health

The criterion on the lack of alternatives presented in the CSS requires that there must be no alternatives that are acceptable from the standpoint of environment and health.

When assessing whether there is a lack of alternatives, "**suitability**" of the alternatives should be considered. The current ECHA definition for suitable alternative requires alternatives to be **safer, technically and economically feasible, and available** in comparison to the controlled substance. Such alternatives should be considered at the level of technical function, end use function, and service function (as per Tickner et al., 2015). Alternatives could be chemicals, materials, processes, product parts, final products, or technologies.

'Safer' in the context of the essential use concept should mean that the alternative entails a lower chemical risk for human health and the environment, from a life cycle perspective, in comparison to the most harmful chemical.

Technical feasibility should consider a level of performance of use which is acceptable for society, i.e., ensuring that the level of performance does not compromise the function that is provided by the substance in the product/process. As such, loss of performance to a certain degree should be acceptable, depending on what level of performance is sufficient and depending on the consequences of the drop in performance. Notably, identification of sufficient level of performance is a challenging task under current assessments of authorisation applications.

Availability, technical feasibility, and economic feasibility should be considered **from a societal point of view, rather than limited to the applicant** e.g.

Defining what economic feasibility from a societal point of view means in practice will most likely rely on political judgement rather than aiming for thresholds which would be specific to the use and vary between sectors, substances, and products.

For scenarios where alternatives exist but are not technically or economically feasible, a substitution plan detailing the commitment to actions and timelines to transfer to alternatives should be provided, as per the current REACH authorisation process.

3.4 Other factors to consider in developing the concept

3.4.1 Order of essentiality assessment steps

Several questions and suggestions from stakeholders refer to the order with which the criteria should be evaluated to be most efficient. For essential uses, all criteria (necessity for health/safety, criticality for the functioning of society, and lack of alternatives) need to be met, therefore the order may not matter. For non-essential uses, disproving one criterion would prevent the need to evaluate the other criterion (therefore saving administrative burden).

Opinions were divisive, with some suggestions that the lack of alternatives should be evaluated first, followed by necessity for health/safety and criticality for the functioning of society, based on the premise that proving the availability of alternatives is simpler (in terms of contentiousness and availability of information needs) and therefore it would be more efficient, for non-essential uses, to first demonstrate that there are alternatives, so that the more difficult assessments of criticality for the functioning of society and necessity for health/safety do not need to be applied. However, other stakeholders stipulated that the assessments of criticality/necessity are simpler and therefore should be undertaken first. Opinions of both NGOs and industry were split between the two.

With clear criteria, the criticality for the functioning of society/necessity for health/safety assessment should be simpler, however, given that assessment of criticality for the functioning of society/necessity for health/safety has not been undertaken before, it is difficult to predict whether this will be less taxing than the assessment of alternatives. This will likely vary on a case-by-case basis.

3.4.2 Conditions for authorisations and derogations from restrictions following the decision on essentiality

Starting point

The essential use concept does not, by definition in the CSS, outline the requirements for risk management of essential uses of the most harmful chemicals. The essential use concept in the Montreal Protocol requires that the production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

> *(i) All economically feasible steps have been taken to **minimise the essential use** and any associated **emission** of the controlled substance; and*
>
> *(ii) The controlled substance is not available in sufficient quantity and quality from **existing stocks of banked or recycled controlled substances**, also bearing in mind the developing countries' need for controlled substances;*

Supporting evidence

Several stakeholders expressed concern that allowing essential uses of the most harmful chemicals based on the essential use concept as per the above criteria (necessity for health, safety, criticality for the functioning of society, non-availability of alternatives), and without considerations of the risks posed by chemicals to human health and the environment, could have negative consequences in cases where a use is essential for society but the risks are insufficiently managed/minimised, e.g. where emissions and exposure result in harm to humans and or the environment. There were also concerns from an industry association regarding who would pay for these costs, for example, if emissions from essential uses must be managed by water operators in additional wastewater treatment steps.

NGOs stressed that the overall aim should be to phase out all uses of the most harmful chemicals, and that the essential use concept must not be interpreted as a free pass to pollute or to slow down the search for safer alternatives. Stakeholders suggested that essential uses must be subject to conditions which incentivise and accelerate substitution, in line with current provisions under similar legislative instruments (e.g. REACH), for example, by making essential use decisions time-limited, requiring reviews after a certain period (and allowing reviews to be requested at any time in case there are changing societal needs or new information on alternatives).

Some stakeholders suggested that downstream users should be requested to perform a substitution plan and that market studies should be undertaken to understand the availability of alternatives.

Considering current REACH, substitution plans are required under Article 62(4) as part of applications for authorisations where suitable alternatives are available. The EU Court judgment in Case T-837/16[84] clarifies that this also applies when suitable alternatives are available in *general* but these alternatives are not *feasible* for the applicant or downstream users. Under the essential use concept, substitution plans could be required when alternatives in essential uses are not

[84] European Commission (2020). Assessment of alternatives: Suitable alternative available in general & requirement for a substitution plan. 27 May 2020.

feasible in the context of wider society (not only the applicant or downstream users). These plans show that effort is being made to move towards substitution of the controlled substance.

Substitution plans should include a description of proposed actions and justifications why those actions are required; who will conduct the proposed actions; a timetable for proposed actions that will lead to transferral to the substitute and justification why the actions require the time allocated; and what the uncertainties are in achieving the actions within the timescale and what possible mitigation is to be considered.

Where there are no alternatives, authorisation applicants are strongly advised (according to ECHA guidance) to include information about any relevant research and development activities by the applicant (in line with Article 62(4)(e) which states that the application shall include this information if appropriate). Plans for R&D play a critical role in fixing the review period (the Commission takes the information into account when deciding the review period). R&D plans should be described in the substitution plan if suitable alternatives are available.

Furthermore, current guidance on derogations from restrictions includes provisions which may be transferrable to the essential use concept to ensure that industry are incentivised to substitute. Notably, derogations may be unconditional, but the concept of 'progress-limited' derogations could be particularly useful under the essential use concept. Progress-limited derogations are contingent upon industry showing that progress in the research on and development on alternatives is actually being made. However, these are currently only applicable for derogations proposed by authorities at the preparation stage of the restriction proposal, where an Annex XV dossier is required and where effectiveness, practicability and monitorability are to be assessed for a derogation. Such a derogation could require industry, for example, to set up monitoring schemes, establish reporting requirements and schedules.

The study on information requirements on uses and exposure in REACH (RPA, Unpublished) describes the type of information required to describe 'Conditions of Use' for downstream users. For example, risk management measures during use and waste processing and operating conditions of processes. This could form a basis for information needed to show that the essential use is minimised and emissions are controlled. It is unclear specifically how authorities could assess whether all economically feasible steps to control the use and minimise emissions have been taken.

Key findings - Conditions for an essential use

For uses derogated from restriction / authorised based on an assessment of essentiality, there must be conditions set in the decision for an essential use to ensure that the use and consequent human and environmental exposure is minimised to avoid risks to human health and the environment from use of the most harmful chemicals, and substitution with safer alternatives is incentivised. As such, the following key considerations should be taken into account when formulating conditions:

- The industry **must take all steps to minimise the essential use and any associated emissions of and exposure to the controlled substance at all lifecycle stages, including waste and recycling, to as low a level as is technically and practically possible**.
- **Time-limited derogations: Essential uses must be reassessed after a specified time period or if there is new information** on alternatives, criticality for the functioning of society, or necessity for health/safety before the end of this time period.
- The derogation should be contingent on demonstration by industry that an **appropriate effort is being made to substitute the controlled substance in the**

use (develop, evaluate, commercialise and secure regulatory approval of alternatives).

For the first condition, it may be appropriate to define and clarify through guidance what is meant in practice by minimisation of the use, emissions, and exposure. In practice, this could be similar to the work of RAC on recommending conditions for risk management measures and operational conditions for uses to be authorised, however, consideration along the full lifecycle of the substance goes one step further. Equally, such minimisation should extend at least to the achievement of the proper control of risks. Requirements to manage risks from OSH legislation could also be considered in guiding how to fulfil the first condition.

Given the recommended condition for the use, emissions, and exposure to be avoided, information provided by industry on the use must be sufficient to allow authorities to assess whether the use meets this condition and therefore could be authorised or derogated from restriction. This would require information on the exact conditions under which the substance is used, as well as information on exposure scenarios, operational conditions, and risk management measures.

The time period for the authorisation / derogation from restriction should be set based on evidence submitted as part of the substitution plan for the essential use, as well as the expected duration of essentiality for society (see the previous section of this report on time scope).

For all essential uses, substitution plans should be used to hold industry accountable to the third bullet point (above). Substitution plans should include commitment to necessary actions in terms of R&D, uncertainties, and contingency measures to address uncertainties.

As per current progress-limited derogations to restriction under REACH, exemptions for essential uses should be contingent upon industry demonstrating progress in R&D. This could require monitoring schemes, reporting requirements, and schedules.

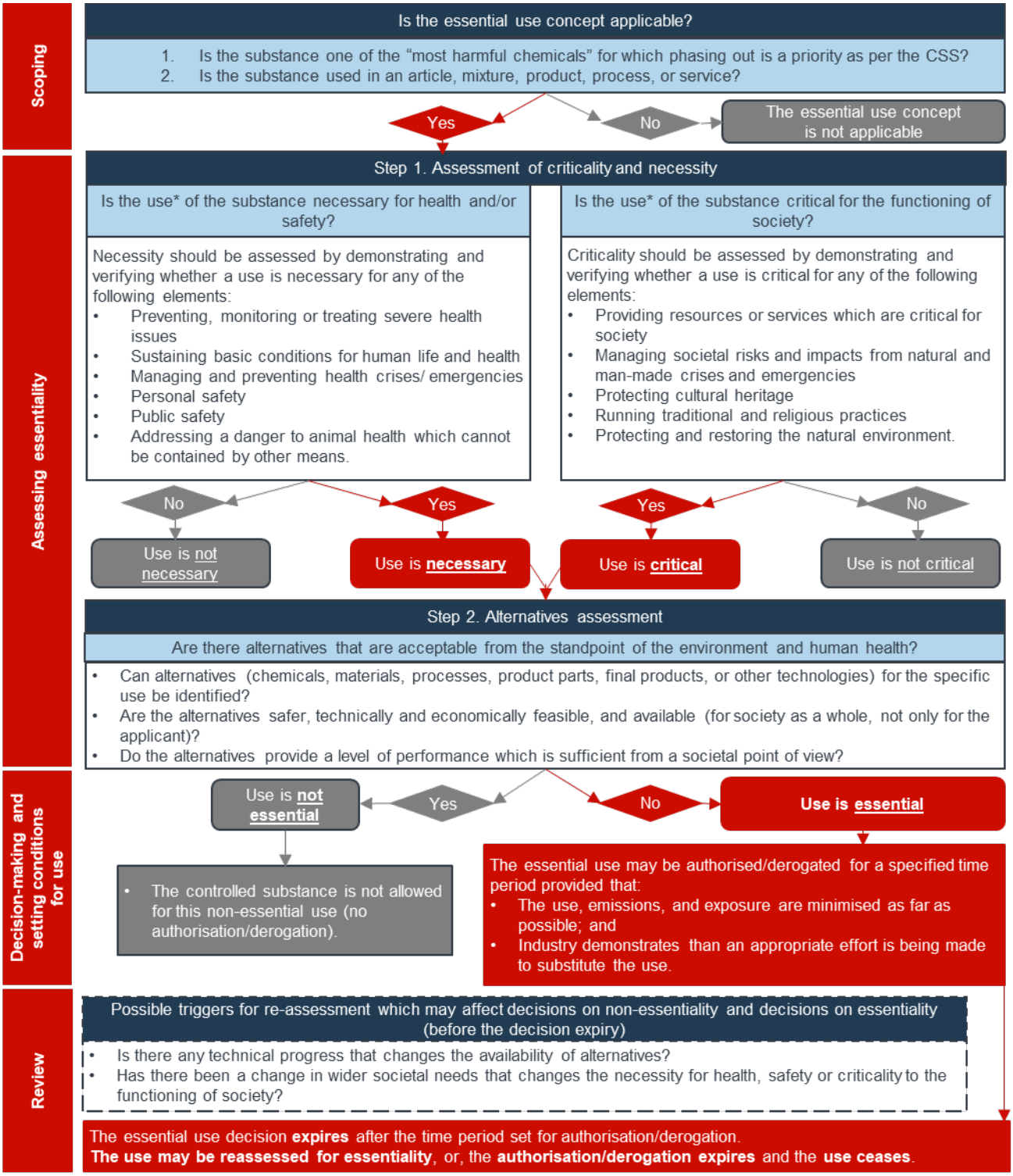
3.5 Summary of findings on the horizontal essential use concept

Based on the conclusions in sections 3.2 to 3.4, the figure below summarises the findings on the horizontal essential use concept in terms of scoping, the assessment and decision-making process, conditions for essential uses, and the review process.

The figure first explains how to discern whether the essential use concept is applicable (scoping). Additionally, this gives an overview of the of the guidance elements which could be considered when assessing whether a use is necessary for health/safety and/or critical for the functioning of society. During this assessment, the assessor should focus on the societal need for the substance to provide a specific technical function in a specific end-use within a defined setting. The alternatives assessment should take into account all types of alternatives (substances, materials, processes, product parts, products, or other technologies) which can replace the use. Finally, decisions for essential uses should be time-limited (due to potential technological advances and changing societal needs) and therefore a review process is shown in the final part of the figure.

The figure represents a high-level overview of findings on the horizontal concept, which should be interpreted in the context of a horizontal guidance (see previous sections). Legislation-specific guidance could complement horizontal guidance, to guide application of the concept in different pieces of legislation which may differ in terms of how the essential use concept can be introduced in practice.

Figure 3.7 Overview of findings on the horizontal essential use concept



* Use should be assessed through considering the societal need for the technical function provided by the most harmful chemical in a specific end use (e.g. final product) in a defined setting.

4 Case studies

4.1 Introduction

As part of this project, a number of specific case studies have been developed. The aim of the case studies was to investigate existing cases under different pieces of EU legislation where chemicals have either been derogated from restrictions or authorised and look at the comparative difference between the 'existing case' (i.e., what has actually occurred in reality) and the hypothetical case where the essential use concept would have been used to assess the derogation/authorisation.

Overall, the objective here was to assess how the essential use concept could have been operationalised in these situations, if applied already, and investigate the impact this might have had (i.e., in comparison with the existing case), including a focus on the following key questions:

- How could the main elements of the essential use concept (necessity for health/safety, criticality for the functioning of society, lack of alternatives) have been assessed in this specific case to inform the decision?
- Would this have improved the effectiveness and efficiency of the process, the level of protection for health/environment, legal certainty, predictability, incentives to substitution, etc.
- What are the key practical challenges in applying essential use to this particular case?
- What would be the impacts if the essential use concept were applied in this case – health/environment, economic, societal?
- What key lessons can we draw from this case for implementing the essential use concept?

The main outcome of developing the case studies was to help elaborate the horizontal essential use concept.

The case studies were developed using a combination of literature review (e.g. using publicly available reports and legislative texts, for example including ECHA reports and decisions), communication with Commission experts, and inputs from wider stakeholder consultation (survey, workshop, interviews).

4.2 Case study overview

The specific case studies covered in this report include the following:

1. REACH restriction of Cadmium;
2. REACH Authorisation of Cr(VI) substances;
3. The regulation of cadmium and lead under Food Contact Materials legislation;
4. Lead in alloys under RoHS;
5. Bis(2-ethylhexyl) phthalate (DEHP) in medical devices;
6. Trichloroethylene under EU Taxonomy legislation; and
7. Anticoagulant rodenticides - Biocidal Products Regulation (BPR).

The full case studies are provided in Appendix B.

4.3 Case study structure

Each case study is presented with a consistent structure, and includes the following sections:

- Introduction;
- Research questions for case study;
- Information sources of evidence used;
- Background context (e.g. on the legislation, substance and its alternatives, use/function, and current situation);
- Application of essential use criteria (feasibility and challenges);
- Potential impact of the essential use concept in this case (e.g. administrative burden, timing of procedure, simplification of the regulatory procedures, predictability);
- Existing gaps in knowledge; and
- Key lessons learned.

4.4 Key findings

In each case study, a number of key findings were specified (see Appendix B) and these have been used to feed into the development of the essential use concept (as discussed in Section 3.3 of Part B in this report) and options for implementation.

It is difficult to determine if/how the outcomes (i.e., a decision on restriction/derogation) of these case studies would necessarily be different under the 'existing' and 'essential use' scenarios as there remain uncertainties in precisely how the concept would be applied or operationalised in specific cases, however, some useful insights have been gained to inform the current project. Briefly, some of the key observations across these case studies are highlighted below:

Practical challenges in defining the horizontal essential use criteria

- The case studies outlined in Appendix B demonstrate the importance of achieving the correct level of 'granularity' in the horizontal criteria defined for the essential use concept (see section 3.3), and that this is a difficult balance to achieve in practice.
- Some of the case studies (e.g. relating to cadmium and the Taxonomy legislation) demonstrate the potential risk of a poorly defined or 'vague' description in relation to a derogation, authorisation or other considerations. It can be considered that the essential use concept, based on more specific criteria, and elaborated in both horizontal and legislation-specific guidance (as discussed in detail in section 3.3), could improve the process in these cases. Increased granularity in criteria could also potentially help 'filter out' 'non-essential' uses for society from essential ones, in cases where applications for authorisations/derogations from restrictions are very broad (e.g. in cases of Cr(VI) or DEHP)
- On the other hand, further granularity of criteria presents the challenge of potentially increased burden relating to increased data submission/assessment to support applications, given that in some cases the 'use' currently covered in existing derogations to restriction/authorisations may include many (thousands) of individual uses and it would need to be determined if these comply with the criteria for necessity

for health/safety, criticality for the functioning of society, and non-availability of alternatives.

- The case studies in this section demonstrate the wide range of potential situations under which the derogation to restriction/authorisation of the most harmful chemicals may be considered, in terms of different uses, functions, data requirements and practical considerations. Each case comes with its own specific nuances and complexities that need to be considered on a case-by-case basis. The development of horizontal criteria that can be used in practice across these myriad of different situations is clearly very challenging.

Practical challenges in implementing the horizontal essential use concept

- The case studies have highlighted that under different scenarios (e.g. for different pieces of legislation), the parties undertaking the assessment may be different, as in some cases (e.g. under REACH) this is based on authority assessment, while in others (e.g. Taxonomy) this is an industry self-assessment. The case studies have also emphasised the need for industry to have clear understanding of what the information requirements are (for example, to understand how the data needs under essential use are different to that under current SEA-based approaches – e.g. as used under REACH and RoHS).
- These considerations highlight the importance of developing clear guidance to inform the implementation of the essential use concept. This could include horizontal guidance, to ensure a consistent understanding across different legislation (e.g. to prevent a lack of coherence, as discussed for Taxonomy and REACH) and legislation specific guidance or provisions. This has been further elaborated and covered in detail in section 3.3 of this report.
- It has been noted (e.g. in the FCM case study) that even if the criteria are clear and specific, in certain cases, when assessing whether such criteria are met, the final judgment may need to involve more subjective and political judgment, (e.g. in case authorities are proposing a derogation for a use they consider essential for society). This has been illustrated in the case of proving criticality for the functioning of society linked to the cultural heritage element.

Potential for improved environmental/health protection

- Several case studies (e.g. relating to cadmium and Cr(VI)) illustrate how the essential use concept could potentially offer a more targeted, more specific, narrower and stricter derogation compared to the existing restriction/authorisation, therefore potentially leading to a more effective elimination of the most harmful chemicals in some cases. This would need to be weighed against the practical and administrative challenge of providing and assessing the necessary data (see below).

Potential for improved efficiency

- A number of case studies have highlighted the importance of the level of details at which the horizontal essential use concept is assessed and how this would then impact how authorisation/derogations to restriction of chemical is achieved.
- Some existing derogations to restrictions/authorisations under REACH cover uses that would clearly be considered ‘essential’ for society but also other uses where this is much less clear (e.g. Cr(VI) in aviation uses – some of which are expected to cover

uses ‘necessary for health or safety’ or ‘critical for the functioning of society’, while others may not be).

- In a number of cases, the improved specificity/granularity of the assessment (as discussed above in relation to cadmium) could have potentially prevented the need for further clarifications, information requests and unnecessary data gathering/assessment, meaning a more efficient process.
- Depending on the specific case, some information currently needed under the SEA route of REACH authorisation may no longer be needed under the essential use concept, depending on the sub-option chosen. On the other hand, the current information requirements in the SEA route of authorisation may need to be amended and require new information that is currently not required. Therefore, the relative difference in the level of burden is hard to predict and will be variable between different cases and depending on the interaction between SEA and the essential use concept. This is further elaborated in the context of REACH, in Part C of the report (section 11.6).
- Cases could be simpler to demonstrate an essential use for society (i.e., demonstration of necessity for health/safety and/or criticality for the functioning of society, and non-availability of alternatives) with reference to health and safety standards or regulations noting that these standards may evolve with time, for example, as regards the acceptability of less but still sufficiently performing alternatives. This has been reflected in the specific elements outlined for the essential use criteria in section 3.3.

Potential for improved predictability

- As discussed, for example, in the case studies relating to RoHS, the essential use concept should bring concrete elements/definition which should be fulfilled for a use to be proven essential for society in the consideration of derogations/authorisations. This would increase the predictability and ease the administrative burden during the process as currently no such elements are defined.
- The essential use concept could provide better predictability, enabling the upfront identification of specific ‘non-essential’ uses for society, indicating priorities for companies’ substitution activities in such uses. This could, for example, deter applications in clearly non-essential uses. However, as noted above, this will not be true in all cases and there will be cases where this is much less clear (as demonstrated by the Cr(VI) example).
- As discussed above, clearly defined essential use criteria could also help remove ambiguity when making assessments on what is considered ‘essential’ for society, either in the context of making decisions on potential authorisations or derogations from restrictions (see example of cadmium) or in implementing other environmental legislation (see example of Taxonomy Regulation).
- In helping to avoid potential ambiguity, the essential use concept can offer an increased level of legal certainty and predictability at the outset (e.g., when the restriction, and associated derogations, are defined).

5 The essential use concept in EU legislation (other than REACH)

5.1 Introduction

The Commission sets out a commitment in the CSS to define essential use criteria to guide the application of the essential use concept horizontally, across legislation.

Part C of this report investigates how the essential use concept could be implemented in REACH and what the expected environmental, social, and economic impacts of this implementation would be.

This section of the report investigates how the essential use concept could be implemented in EU legislation **other than REACH**, based on legislation reviews conducted under Task 1 and 2, as well as inputs from stakeholders as part of the consultation activities.

Stakeholders were divided on whether the essential use concept could bring benefits to pieces of legislation other than REACH (see Figure 5.1). Public authorities, NGOs, and academia favoured implementation of the concept in legislation other than REACH, while business associations were strongly against implementation in other legislation. Marginally more companies were against, rather than in support of, implementation in other legislation.

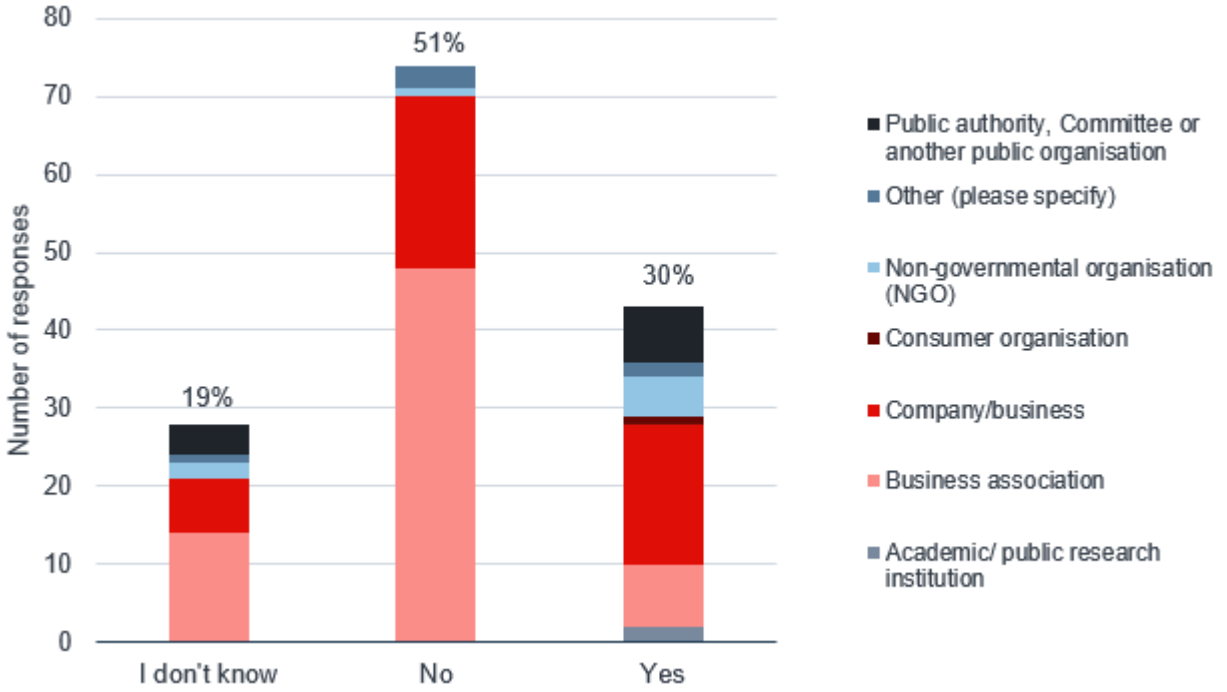
Stakeholders who predicted benefits of implementing the essential use concept in legislation other than REACH were asked to elaborate. Some general comments were received, supporting implementation in all legislation or all product-specific legislation. One member of academia and two public organisations suggested that recommendation for use in other legislation should depend on how the concept is fully developed.

Named pieces of legislation suggested to potentially benefit from an essential use concept are shown in Figure 5.2 (presenting the frequency of mention of each piece of legislation).

Several respondents, who had answered ‘yes’, identified that many pieces of legislation on specific uses of substances or applications could benefit from the essential use concept. One business/company supported the inclusion of many pieces of legislation due to the health and environmental impacts attributed to hazardous substances. Others highlighted that the use of an essential use concept could improve alignment of multiple pieces of legislation. One example provide was the potential to improve coherence between Restriction of Hazardous Substance Directive (RoHS) and End-of-life Vehicles (ELV) legislation (see below).

It was also noted that the applicability of the concept to other legislation should not occur until a framework has been established under REACH. Stakeholders selecting ‘yes’ were invited to further elaborate which pieces of legislation they thought would benefit from the implementation of the essential use concept. Furthermore, there were comments that the concept is already adequately present in RoHS and the Cosmetic Products Regulation.

Figure 5.1 Targeted survey responses to the question "Do you think there are pieces of legislation other than REACH that would benefit from an essential use concept?" (n = 145)

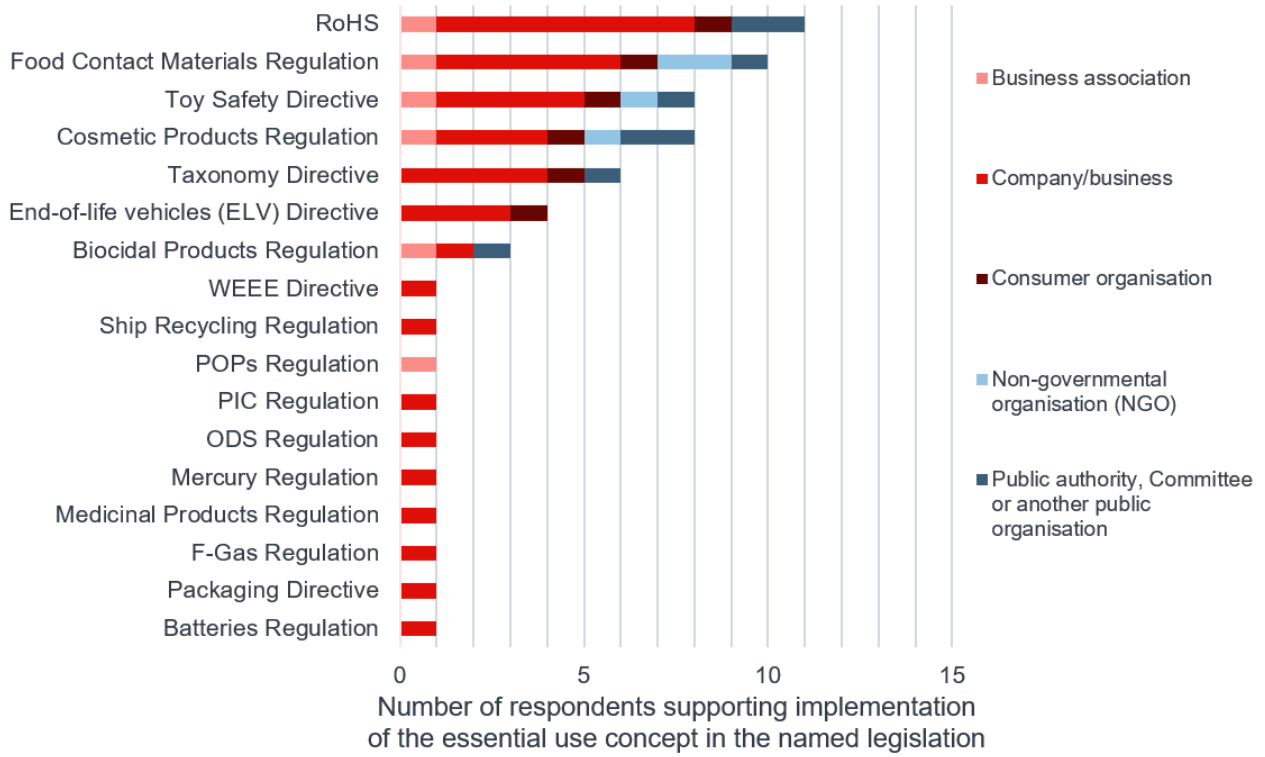


20 stakeholders elaborated on this answer by naming pieces of legislation which they thought could benefit from the essential use concept. This is depicted in Figure 5.2 below.

It should be noted that several of these 20 stakeholders suggested multiple pieces of legislation that would potentially benefit from the essential use concept. The figure below is based on a summation of all suggestions made across these 20 responses (60 total suggestions made).

Importantly, the level of support for each piece of legislation is hard to assess with the small sample size, for example, 10 pieces of legislation were only named by one respondent each. The RoHS Directive, Food Contact Materials Regulation, Toy Safety Directive and Cosmetic Products Regulation were the most popular choices (a result which may be influenced by the inclusion of these pieces of legislation as examples in the text of the previous question).

Figure 5.2 Named pieces of legislation other than REACH that would benefit from an essential use concept as indicated by stakeholders responding to the targeted survey. (n=60)



Information on how the essential use concept could be applied in the most commonly suggested pieces of legislation has been synthesised in the following sections based on a review of available literature, consultation with Commission experts, inputs to the targeted survey, inputs from targeted interviews, and the stakeholder workshop.

5.2 RoHS Directive

5.2.1 Starting point

The **RoHS Directive**[85] (Art.4(1)) prohibits the use of certain hazardous substances and substance groups[86] above a specified maximum concentration by weight in homogeneous materials (listed in Annex II).

As a derogation to this restriction, Annexes III and IV (exemptions) list specific uses for which the restricted substances are allowed. The criteria for deciding whether to include uses in these lists are set in Article 5. Specifically, uses may be included in these lists provided that inclusion does not weaken the environmental and health protection afforded by REACH and where any of the following conditions is fulfilled:

- Their elimination or substitution […] is scientifically or technically impractical;

[85] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
[86] Lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

- The reliability of substitutes is not ensured; and
- The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

These conditions are similar to the essential use criterion on 'lack of alternatives that are acceptable from the standpoint of environment and health' (see section 3 of this part of the report). The conditions are cumulative and in order to exempt a use form the ban, all of them need to be fulfilled. The first bullet point considered whether elimination or substitution of the banned substance is technically practicable. This criterion may therefore be considered similar to the criterion on 'the lack of alternatives'. Also, the second bullet point is similar to the essential use criterion on lack of acceptable alternatives, although expressed differently and alluding to technical feasibility of alternatives. This is however only one component of 'acceptability' of alternatives to be considered when assessing alternatives (section 3). It is noted that under the essential use concept, alternatives need to be 'acceptable' from the standpoint of environment and health.

The third bullet point is similar, but not exactly the same as the requirements under the essential use concept for alternatives to be acceptable from the standpoint of environment and health. This requirement under RoHS involves weighing risks against benefits of substitution, which is not explicitly the focus under the essential use concept. Under RoHS the approach is a socio-economic consideration from substitution and comparison of impacts between the controlled substances and the substitute. If the substitute causes more negative impacts than continuation of use of the controlled substance, an exemption can be given.

In addition, RoHS does not currently take into account the necessity of a use for health/safety or the criticality of a use for the functioning of society. Therefore, a use may be derogated if there are no alternatives available even when the use is not necessary for health/safety or critical for the functioning of society, demonstrating that the essential use concept would result in more strict restrictions (with fewer exemptions) than the current provisions under RoHS.

It is noted that technical applications with a valid exemption entry cannot be revoked under RoHS if revocation would result in severe negative impacts on society (e.g. lead in medical devices or lead in steel). The derogations are reviewed according to their expiry dates.

5.2.2 Supporting evidence

Stakeholders at the workshop and respondents to the survey agreed that the RoHS Directive already contains similar aspects to the essential use concept regarding the alternative assessment.

The substances restricted under RoHS qualify as the most harmful chemicals and therefore are relevant for application of the essential use concept.

In the stakeholder survey, RoHS was suggested most frequently (by 11 respondents) as having the potential to benefit from the essential use concept, indicating that several stakeholders consider the essential use concept would support decisions regarding restrictions and/or exemptions for uses of substances in electrical and electronic products.

There was also a discussion of the benefits and challenges around applying the essential use concept in RoHS during the stakeholder workshop. An industry stakeholder suggested that a horizontal essential use concept could increase coherence and harmonisation across adjacent legislation. Coherence between RoHS and the ELV Directive was provided as an example, given that they both aim to restrict hazardous substances and their coherence has previously been criticised by stakeholders[87]. A horizontal essential use concept could allow harmonisation between

[87] European Commission. Have your say, End-of-life vehicles - revision of EU rules (public consultation). Retrieved 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12633-End-of-life-vehicles-revision-of-EU-rules/public-consultation_en.

the methods to exempt uses of hazardous substances from restrictions under both pieces of legislation. There was consensus that increased coherence with adjacent legislation, e.g. ELV, would be beneficial, and that the essential use concept may lead to such harmonisation.

Other stakeholders also expressed interest in seeing RoHS and REACH better aligned, therefore adopting a common essential use concept could be viewed as a means to improve this alignment. Importantly, the RoHS Directive specifies in Article 5 that inclusion of any use in Annex III or IV (exemption from restriction) must *"not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH)"*. To ensure that the environmental and health protection afforded by both REACH and RoHS are aligned, the essential use concept could be implemented so that rationale for exempting uses of the most harmful chemicals is the same for both pieces of legislation.

Some stakeholders from industry and authorities cautioned that changing the currently functional system requires attention to detail to avoid any negative impact on the efficiency of RoHS, and therefore must be carefully considered before recommending the implementation of the essential use concept. However, despite claims that the current system works well, it is important to note that the evaluation of the RoHS Directive found that there are issues with the current provisions for setting exemptions, e.g. based on overly complex rules on exemption validity and issues arising from the applicability of criteria for exemptions.[88] The essential use concept could therefore address these issues, although an impact assessment would be needed to validate this.

Other stakeholders noted that the existing criteria for the assessment of exemptions from the RoHS restrictions are broad and that they could open up the possibility to interpret the criteria in an inconsistent way. One stakeholder noted that the essential use concept should not be included in the RoHS Directive due to the disproportional impact it could have on sectors such as the medical device sector. Here it was noted that the costs of redesigning an old piece of technology to remove, e.g. lead, could equal the costs of developing a new product.

Member State authorities at the workshop noted the flexibility of the current mechanisms under RoHS (e.g. regular review, with stakeholders able to apply for granting or removing derogations). The stakeholders discussed if, and how, the existing flexibility should be preserved while also providing the certainty required by industry as a basis for investment choices.

At the workshop, industry stakeholders urged the incorporation of a fall-back mechanism for cases in which alternatives fail after some time in daily use. It was pointed out, that due to long service times of products regulated under RoHS, an alternative first deemed suitable could fail after years, possibly with severe consequences.

5.2.3 Conclusion

The criteria for derogations/exemptions in RoHS are partly similar to those in the essential use concept as there is a consideration similar to those for the availability of alternatives (although the term is not used explicitly in the legislation). However, the consideration of 'essentiality for society' is not made explicitly and regard for the criticality for society and necessity for health/safety of a use is absent. The application of the essential use concept in the RoHS Directive could be done by replacing the existing provisions of Article 5.

Overall, RoHS is the most supported piece of legislation other than REACH for implementation of the essential use concept.

A horizontal essential use concept also offers the potential for closer alignment and better coherence with other EU legislation (e.g. the End of Life Vehicles Directive which also deals with

[88] European Commission. Have your say, Review: Restriction of the use of hazardous substances in electronics (public consultation). Retrieved 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13137-Review-Restriction-of-the-use-of-hazardous-substances-in-electronics_en.

electronic waste; and REACH which also regulates the substances restricted by RoHS), for example by applying the same derogation criteria.

The exemption criteria are being reviewed in the currently ongoing review of the RoHS Directive. The call for evidence[89] highlighted that the reform of the exemption process is a possible option to address current problems RoHS, however, it is unclear at this stage whether any consideration of the essential use concept is being made. The revision of RoHS is ongoing and could provide an opportunity for incorporation of the essential use concept.

5.3 Food contact materials (FCM) legislation

5.3.1 Starting point

The main EU legislation for food contact materials (FCMs) is Regulation (EC) No 1935/2004, which sets out the basic requirements including on chemical safety and under which, several pieces of legislation also exist on specific FCM materials.

Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food[90] sets out rules on the composition of plastic FCMs and establishes a 'Union List' of substances, e.g. monomers, starting substances, additives and polymer processing aids, that are permitted for use in the manufacture of plastic FCMs subject to certain derogations. Regulation (EC) No 450/2009 establishes rules on active and intelligent materials and articles intended to come into contact with food[91] and provides for the introduction of a Union list of substances permitted for the manufacture of active and intelligent materials. Further rules exist on good manufacturing practice (GMP), recycling of plastic for FCM, ceramic FCM, regenerated cellulose film and on various specific substances.

Primarily, the rationale used for deciding whether or not a substance may be used in food contact materials depends on adherence to the principles of safety and inertness of FCMs as set out in Regulation (EC) No 1935/2004 which requires that materials do not release their constituents into food at levels harmful to human health or change food composition, taste and odour in an unacceptable way.[92] This premise, based on safety rather than criticality for the functioning of society or necessity for health/safety of the use and availability of alternatives, differs substantially to the essential use concept.

Revision of the EU legislation on FCMs was announced in May 2020 and will reflect the findings of the FCM Evaluation. An inception impact assessment has been published[93]. One objective in the inception impact assessment is prioritising the assessment and management of substances. In this regard it states that "the essential uses of substances in FCMs will need to be defined taking into account the necessity of the final FCM together with replacement possibilities in order to inform on the possibility for exceptional derogations and consistent with the approach resulting from the Chemical Strategy," therefore, it is likely that the essential use concept will be considered for application in FCM legislation.

[89] European Commission. Have your say, Review: Restriction of the use of hazardous substances in electronics (public consultation). Retrieved 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13137-Review-Restriction-of-the-use-of-hazardous-substances-in-electronics_en.
[90] Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
[91] Commission Regulation (EU) No 10/2011 on active and intelligent materials and articles intended to come into contact with food.
[92] Regulation (EC) No 1935/2004 of the European Parliament and of The Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
[93] European Commission. Have your say, Revision of EU rules on food contact materials (public consultation). Retrieved 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en.

5.3.2 Supporting evidence

FCM legislation[94] was mentioned by 10 respondents as potentially benefiting from the implementation of the essential use concept (the second most frequently mentioned piece of legislation). Five of these respondents were companies, three were business associations and two were NGOs.

An NGO responded to the targeted survey supporting application of the essential use concept in FCM legislation on the basis that the use of some chemicals in FCMs is non-essential for society and therefore the essential use concept could facilitate phasing out many non-essential uses of the most harmful chemicals from FCMs. For example, the use of per- and polyfluoroalkyl substances (PFAS) for non-stick cookware and the use of other most harmful chemicals as colourants, which stakeholders argued there are available alternatives for. This same argument was supported by another NGO in the workshop and in a position paper from a research institute.

One respondent noted that the current approach to regulating FCMs does not guarantee the absence of the most harmful chemicals. Their reasoning was that not all harmful substances are covered under the current regulatory framework for FCMs and that chemicals considered as most harmful chemicals under the Chemicals Strategy for Sustainability are present in several FCM types and can migrate into food. Therefore, they indicated that the EU's Framework Regulation on FCMs could greatly benefit from integration of the essential use concept which could allow the regulation to more easily and effectively manage harmful substances in FCMs, increasing their safety.

In addition, stakeholders noted that the integration of the essential use concept in FCM legislation could support other EU targets such as the transition towards a circular economy through increased recycling rates by reducing the overall chemical complexity of materials.

However, a number of industry representatives were not in support of applying the essential use concept in FCM legislation. At the workshop, one industry association argued that there are already existing systems in place to consider derogations for the restriction of substances of concerns in FCM (e.g. the use of substances in FCMs must comply with REACH (with some exemptions) and therefore could be subject to REACH authorisations for example). It is noted, however that not all substances used in FCM will necessarily be regulated under REACH and while there may be substances regulated in FCM that may also be regulated under REACH, for example due to their hazardous properties for the environment. One Member State authority argued against the implementation of the essential use concept in FCM regulations because of the opinion that the positive list approach works well and there is no need to change it. The stakeholder suggested instead to expand the existing legislation to consider environmental safety aspects. It is noted that the Commission intend to do this, and this is not seen as contradictory to the implementation of the essential use concept.

Although implementation of the essential use concept would indeed change the current approach substantially, the project team found no reason why the concept could not be implemented in the positive list approach. For example, instead of basing the positive list only on the safety of use, there could be considerations for essentiality of the use for society. Furthermore, since the essential use concept is only applicable to the most harmful chemicals, for which there is an ambition to rely more on the generic approach to risk management (GRA), the essential use concept will therefore be more relevant within the future application of the GRA in FCM legislation, rather than in its current form.

It would need to be considered if the requirement for the minimisation of use and exposure/emissions for uses determined to be 'essential' for society would be considered compatible with the positive list approach to ensure safety of use. As noted in section 3.3 of this

[94] Regulation (EC) No 1935/2004 of the European Parliament and of The Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

report, even if a use is determined to be 'essential' for society, the exposure/emissions should be minimised as far as possible, e.g. even beyond the adequate control in case of threshold substances. This would need to be further considered in the ongoing revision of FCM legislation.

The issue of the application of the essential use concept in FCM legislation was also discussed with stakeholders during the workshop and in targeted interviews. During the workshop, there was no consensus amongst the stakeholders if the essential use concept should be applied in FCM regulations.

In addition to stakeholder views, it should be noted that there has been political recognition of current limitations in the FCM legislation. For example, the Commission notes in the CSS that consumers are widely exposed to chemicals present in FCMs and commits to extending the generic risk management approach to FCMs. The inception impact assessment for the revision of FCM legislation[95] also recognises that FCM legislation currently lacks coherence in taking a more preventative approach in regulating certain substances compared to other legislation. As such, implementation of the essential use concept could be aligned with political ambition to improve how the most harmful chemicals are regulated under FCM legislation.

5.3.3 Conclusion

FCM legislation is currently undergoing revision with consideration of the implementation of the essential use concept. Implementation of the essential use concept in the legislation could help achieve the political ambition to improve how the most harmful chemicals are regulated in FCMs and to improve coherence with regulatory approaches in other EU legislation.

The essential use concept offers the potential to strengthen the legislation with a consistent definition of 'essentiality' for society applied horizontally across different legislation, therefore improving the coherence with other legislation and the overall speed of phasing out harmful substances in non-essential uses and the transition to safer alternatives in essential uses. This may also establish safer and more sustainable alternatives, enabling more effective recycling of materials, improving the performace of this sector with regard to circular economy targets.

However, a number of key challenges that will need to be addressed when applying the horizontal concept in this sector have been identified (see discussion above earlier in this section). It is noted that in practice, considerations for FCM need to be determined by e.g. DG SANTE or EFSA, as there is specific chemicals legislation on FCM managed by DG SANTE and where the risk arises from food for which ESFA has the expertise. This is expected to remain the case going forward, so the question remains as to whether the decisions on essential use should fit within this current system or whether for example, they can be made by another committee or body.

For example, while it is expected that the criteria set out in Table 3.1. (section 3.3.2) for 'necessity for health and safety' will be relevant in this sector, specifically where this refers to food safety and hygiene, there will need to be clear guidance for industry for how to interpret and demonstrate 'essentiality' for society in applying for derogations for the use of one of the most harmful chemicals in FCM materials specifically.

[95] European Commission. Have your say, Revision of EU rules on food contact materials (public consultation). Retrieved 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en.

5.4 Toy Safety Directive

5.4.1 Starting point

Directive 2009/48/EC on the safety of toys sets out rules aiming to ensure that toys are safe for the user. Specifically, Article 10 states that toys may not be placed on the market unless they comply with specified safety requirements. Manufacturers are therefore required, before placing a toy on the market, to carry out an analysis (in the form of a specific safety assessment) of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to the user to such hazards (Article 18).[96]

Annex II Part III (chemical properties) requires that toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to chemical substances or mixtures of which the toys are composed or which they contain. It also bans CMR (category 1A, 1B or 2) substances from being used in toys, with exemptions where certain conditions are met. These conditions include low concentration uses, uses where the substances and mixtures are inaccessible to children, and uses where a decision has been made by the Commission to permit the use.

Decisions to permit the use of CMR substances may be taken by the Commission if:

1. their use has been evaluated and found to be safe by the relevant scientific committee in particular in view of exposure (applies to category 1A, 1B and 2);
2. there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives (applies to category 1A and1B only); and
3. the substance is not prohibited for use in consumer articles under REACH (applies to category 1A, 1B and 2).

There is not, therefore, an explicit consideration of ‘essentiality for society’ when considering potential derogations. Current derogations are made based on safety (concentration, predicted exposure to children, and evaluation by the Scientific Committee on the basis of the criteria referred to above). For the derogation based on a Commission decision and an evaluation by a Scientific Committee, the second condition (listed above) is similar to the essential use criterion on availability of alternatives, however, the current directive does not refer to necessity for health and safety or criticality for the functioning of society. As such, other derogations in the Directive allow for the presence of CMRs where concentrations are low or where they are inaccessible to children.

So far only one use has been exempted by a decision taken by the Commission, which is the use of nickel[97] in toys and toy components made of stainless steel and in toy components which are intended to conduct an electric current.

Only CMRs, as a subset of the most harmful chemicals, are subject to generic bans under the directive, showing a lack of provisions for other hazard classes of the most harmful chemicals (e.g. endocrine disruption) under the legislation, except for falling under the scope of specific risk assessment of toy safety.

[96] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.
[97] Commission Directive 2014/84/EU of 30 June 2014. Amending Appendix A of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards nickel.

The Directive is currently undergoing revision, with adoption planned in 2023. An Inception impact assessment and summary of findings from the public consultation on the revision (which ran between March and May 2022) have been published[98].

5.4.2 Supporting evidence

The **Toy Safety Directive** was mentioned by 8 respondents as potentially benefiting from the implementation of the essential use concept.

Although several respondents believed that the Toy Safety Directive would benefit from the essential use concept, as indicated in Figure 5.2, there was limited further information available in the targeted survey to suggest why this is the case. One argument made in the workshop by a member of academia in favour of integrating the essential use concept within the Toy Safety Directive was that toys do not need to be made of a specific material, meaning it may be easier to substitute certain chemicals. This relates to the essential use criterion on lack of alternatives, for which section 3 of this report concludes should allow a loss of performance which is acceptable for society. Notably, analysis of alternatives already comprises a part of the decision making for derogations of uses of CMRs in toys and so this consideration could be made without the essential use concept.

One industry respondent to the survey indicated that they considered the essential use concept would be of no benefit to the Toy Safety Directive. They noted that the objective of the Toy Safety Directive is to ensure toys do not jeopardise the safety and health of users, and so the assessment should be based on risk (which is dependent on exposure), and not essentiality for society. Therefore, they do not believe that the essential use concept is in line with the objectives and provisions of this Directive. It is important to note, however, that the essential use concept is intended to improve protection of human health and the environment through a more preventative approach of only allowing uses which are essential for society, and for which risk management conditions will be set to minimise the use, emissions and exposure.

An industry representative argued that the essential use concept would not necessarily strengthen coherence given that substances in toys may be subject to REACH restrictions and authorisations. This is because substances in toys are within the scope of REACH, both for environmental purposes but also for human health.

However, while Annex II part III of the Toy Safety Directive refers to REACH prohibitions of consumer uses in decision-making by the Commission to derogate uses in toys, it does not refer to REACH when permitting derogations based on low concentration or inaccessibility to children. This shows a potential incoherency if REACH were to only allow derogations based on the essential use concept while the Toy Safety Directive allows derogations based on other reasons. Furthermore, the Toy Safety Directive does not include reference to environmental safety as it focuses on protection of consumers. Lastly, the current directive is limited to generic bans of CMRs as a sub-set of the most harmful chemicals and relies on specific risk assessment to address other chemical risks.

5.4.3 Conclusion

The inception impact assessment for the revision of the Toy Safety Directive envisions extending the generic risk management approach currently embedded in the Directive only for CMRs to other ‘most hazardous substances’ to health such as endocrine disruptors (i.e., certain substances

[98] European Commission). Have your say, Protecting children from unsafe toys and strengthening the Single Market – revision of the Toy Safety Directive. Retrieved 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13164-Protecting-children-from-unsafe-toys-and-strengthening-the-Single-Market-revision-of-the-Toy-Safety-Directive_en.

described as the 'most harmful chemicals' in the context of the CSS) and to revise the derogations from the general prohibitions of CMRs.

Applying a horizontal essential use concept, as envisioned here, offers a potential route to applying this in such a way that achieves coherence with REACH (i.e. applied to the same scope of substances, the 'most harmful chemicals') and then enabling Toy Safety Directive to introduce further measures to restrict substances that are allowed under REACH to ensure user safety). For example, the Inception Impact Assessment indicates that the revision would look to extend the generic risk assessment to: "other most hazardous substances such as endocrine disruptors or substances that are persistent and bioaccumulative. However, further feedback from the Commission noted that the proposed revision of the TSD is covering only health-related most harmful chemicals (i.e., not PBT/vPvB) so this environmental protection aspect would be covered under REACH still, as with the Cosmetic Products Regulation (see below).

In practice, the need for, and application of, the essential use concept in this directive will need to be carefully considered. It is noted that the existing derogation system for toys already has very strict requirements and as such some argue there is not a need to replace it. For example, the existence of only one current derogation for CMR shows that the current system is successful in reducing the use of CMR substances (although it is unclear how this would change if more hazard classes were included in the generic ban).

5.5 Cosmetic Products Regulation (CPR)

5.5.1 Starting point

Article 15(1) of the Regulation (EC) No 1223/2009 on cosmetic products prohibits the use of CMR substances, categories 1A, 1B and 2, in cosmetic products.[99] Derogations to this rule may be made if all of the criteria under Article 15(2) apply. Individual substances and substance groups are prohibited if listed in Annex II of the regulation, or in Annex III subject to certain conditions (for each entry, product types, maximum concentrations, and conditions of use may be set).

The use of CMR substances (cat 1A/1B) may be allowed if all of the following criteria are met:

- they comply with the food safety requirements as defined in Regulation (EC) No 178/2002;
- there are no suitable alternative substances available, as documented in an analysis of alternatives;
- the application is made for a particular use of the product category with a known exposure; and
- they have been evaluated and found safe by the SCCS for use in cosmetic products and taking into consideration the overall exposure from other sources and vulnerable population groups.

Similarities may be drawn to the essential use concept as the approach to derogations for CMR substances (cat 1A/1B) in the Cosmetic Products Regulation (CPR) requires that suitable alternatives are not available. Both the current legislation and the essential use concept also require (in different words) that derogated uses are sufficiently controlled so that risks to human health are avoided. The essential use concept could introduce more stringent conditions for derogations as only uses which are necessary for health/safety or critical for the functioning of society (as well as being safe and having no available alternatives) could be derogated. Furthermore, the CPR could be adapted to extend the scope of the generic risk management

[99] Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

approach from CMRs to other hazard classes which fall under the definition of the most harmful chemicals in the CSS. This would align with the horizontal essential use concept which could be applied to the same scope of substances (to the 'most harmful chemicals').

The CPR is currently undergoing revision, with a legislative proposal is anticipated in 2023. An inception impact assessment has been published[100]. The revision of Article 15 is envisioned as part of this process. An open public consultation looking into this legislation ran from March to June 2022[101]. One question in the open public consultation asks to what extent the essential use concept is needed in the Cosmetics Products Regulation as part of the application of the Generic Approach to Risk Management.

5.5.2 Supporting evidence

The **Cosmetic Products Regulation**[102] was mentioned by eight respondents as potentially benefiting from the implementation of the essential use concept.

Some respondents highlighted that the Cosmetic Products Regulation is based on a very detailed and targeted assessment of the safety of cosmetic products/use of ingredients to the user. These respondents indicated that the existing mechanism for derogating CMR substances in this Regulation has shown that there are exceptional cases where the use of a CMR substance can be demonstrated to be safe, fulfilling other conditions for derogations and compatible with a high level of consumer protection. Respondents raised concern that only allowing the uses when essential for society would be disproportionate as they argued that risks are already sufficiently controlled without the essentiality considerations. Furthermore, respondents were concerned that the essential use concept could make it very difficult to apply for derogations. When considering these concerns, it should be kept in mind that the aim of the essential use concept is to phase out the uses of the most harmful chemicals for all non-essential uses while giving more time for the substitution in essential uses, which inevitably relies on stricter derogations.

5.5.3 Conclusion

There is no explicit implementation of the essential use concept currently in the CPR as the assessment of cosmetic products is primarily done on the grounds of safety. There is a requirement to look at alternatives and overall exposure from other sources (i.e., other than cosmetics), linked to derogations under Article 15(2).

The inception impact assessment for the revision of this legislation indicates that options are being assessed to bring Article 15 in line with the essential use concept. It was identified by the Commission that the specificity of the cosmetics regulation needs to be taken into account in the possible application of the essential use concept.

It can be expected that the issue of 'health and safety' will be a key consideration when looking at the essential use concept in the context of the CPR. Indeed, it is a (legal) priory of the Regulation that cosmetic products placed on the market must be safe for the user, therefore alignment of or complementarity with this provision with the conditions for essential uses (to ensure the use, emissions and exposure is minimised as far as possible) should be sought.

Certain uses of substances in cosmetics may be considered necessary for health or safety or critical for the functioning of society in view of their use as preservatives (e.g. keeping products

[100] European Commission, (2021). EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision). Retrieved on 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13197-EU-chemicals-strategy-for-sustainability-Cosmetic-Products-Regulation-revision-_en
[101] European Commission, (2022). EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision). Retrieved on 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13197-EU-chemicals-strategy-for-sustainability-Cosmetic-Products-Regulation-revision-/public-consultation_en
[102] Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

safe for the consumer), UV filters (e.g. reducing the risk of skin cancer), anticaries agents (e.g. contributing to oral health care), etc.

The Commission is assessing the possibility to expand the generic approach to risk management to other hazardous substances to health beyond CMRs (e.g. EDCs, etc.) in the revision of the Cosmetics Regulation. It is noted that it is not currently considered to include key hazard classes relevant to environmental protection (e.g. PBT/vPvB) under the revision of the CPR. The application of the essential use concept could, therefore, be considered for the same scope of substances (i.e., 'most harmful chemicals') as a derogation criterion and could possibly offer a potential means of coherence with other legislation that may restrict 'the most harmful chemicals'. However, REACH will continue to cover restrictions (and derogations) relevant to environmental protection relating to these substances.

5.6 Taxonomy Regulation

5.6.1 Starting point

Regulation (EU) 2020/852 (the Taxonomy Regulation) establishes the general framework for determining whether an economic activity qualifies as environmentally sustainable based on its interaction with the six environmental objectives[103] set out by the regulation. Technical screening criteria are set out for each environmental objective to determine whether an economic activity is sustainable (i.e., aligned with the objectives and does not significantly harm any of the objectives).

Appendix C[104] to Commission Delegated Regulation (EU) 2021/2139 specifies generic criteria for do no significant harm (DNSH) to pollution prevention and control regarding use and presence of chemicals. **The criteria include requirements that the activity does not lead to the manufacture, use, or placing on the market of certain substances**, e.g. those restricted by the Persistent Organic Pollutants Regulation (2019/1021/EU)[105], mercury, those restricted by the Regulation on substances that deplete the ozone layer (1005/2009/EC), among others. In particular, an activity which does no significant harm to pollution prevention and control must not lead to the manufacture, use, or placing on the market of SVHCs as defined by Article 57 of REACH, except for where their use has been proven to be "**essential for the society"**. The regulation therefore includes similarities to the essential use concept as it sets provisions for assessing the essentiality of the use of a chemical for society. However, it does not define these terms. The Regulation does not aim to restrict or derogate uses of chemicals, but to assess them so that the sustainability of economic activities of companies and investors are transparent to facilitate sustainable investments.

5.6.2 Supporting evidence

The **Taxonomy Regulation**[106] was mentioned by 6 respondents as potentially benefiting from the definition of the essential use concept. The horizontal essential use concept could provide a more specific definition to the current broad term of "essential to the society" within the Taxonomy Regulation.

The lack of definition of the current term opens the potential risk of poor alignment, if for example, different criteria were to be used to establish "essentiality for the society" under the DNSH criteria.

[103] Climate change mitigation, climate change adaptation, the sustainable use and protection of water and marine resources, the transition to a circular economy, pollution prevention and control, and the protection and restoration of biodiversity and ecosystems.
[104] Generic criteria for DNSH to pollution prevention and control regarding use and presence of chemicals
[105] Regulation (EU) 2019/1021 of the European Parliament and of the Council on persistent organic pollutants.
[106] Regulation (EU) 2020/852 of the European Parliament and of the Council on the establishment of a framework to facilitate sustainable investment.

The application of the horizontal essential use criteria here could be considered a more effective approach than the current process, and if applied correctly, could make it easier for companies to navigate. There was no further input from the targeted survey to support the use of the horizontal essential use concept within Taxonomy Regulation. Further consultation with industry through targeted surveys was not conducted for this legislation. A more detailed discussion of this legislation in the context the application of the essential use concept for a specific SVHC is provided in the case studies (see section 4).

5.6.3 Conclusion

While the delegated act for the DNSH criteria under Appendix C explicitly mentions that uses shall be proven 'essential for the society', there is no specific definition or criteria for what this means. Therefore, the horizontal essential use concept as being developed in this project offers an opportunity for a coherent application also with the Taxonomy Regulation.

As noted in the case study (see section 3), the terminology is not consistent between the DNSH criteria under Appendix C and the essential use concept criteria. While the essential use concept sets out a detailed criteria of demonstrating a substance is necessary for health and safety or is critical for the functioning of society AND there are no available alternatives which are acceptable from a standpoint of the environment or human health, the Appendix C description refers only to the broader term 'essential to the society'.

It is noted that the process for demonstrating compliance with the DNSH criteria under the Taxonomy Regulation is a 'self-regulated' process for industry to follow. A key to successful implementation (as well as enforcement/monitoring) will therefore be provision of clear and helpful guidance to industry to fully understand the process and the requirements for demonstrating what is 'essential for the society' in this context. Application of the horizontal essential use concept could therefore bring clarity to the meaning of 'essential for society', coherence with other EU legislation which applies the essential use concept, increased overall effectiveness and reduced administrative burden.

5.7 End-of-life Vehicles (ELV) Directive

5.7.1 Starting point

The ELV Directive (Directive 2000/53/EC) encompasses a general restriction on certain hazardous chemicals, with specific exemptions as detailed in Annex II.[107] Article 4 (2)(a) states that "Member States shall ensure that materials and components of vehicles put on the market after 1 July 2003 do not contain lead, mercury, cadmium or hexavalent chromium other than in cases listed in Annex II under the conditions specified therein". Annex II (listing specific exemptions) can be amended on a regular basis, in order to exempt certain materials and components of vehicles if the use of these substances is unavoidable.

Exemptions can be made under the condition specified in Article 4 (2)(b)(ii): The Commission is empowered to "exempt certain materials and components of vehicles from point (a) of this paragraph if the use of the substances referred to in that point is unavoidable".

Based on this process, certain hazardous metals are exempted for specific applications in certain parts of vehicles. For example, lead in high melting temperature type solders (i.e., lead-based alloys containing 85% by weight or more lead). The alternatives' performance is compared, and there is reasoning, why the slightly increased performance of the lead containing material is required in these uses.

[107] Directive 2000/53/EC of the European Parliament and of the Council on end-of life vehicles.

Conversely, exemptions listed in the previously mentioned Annex II may be deleted from the annex if their use is deemed avoidable (when it was previously considered unavoidable). Both actions require delegated acts by the Commission to "on a regular basis, adapt to the technical and scientifical progress".

The ELV Directive in undergoing review of legislation[108]. A roadmap for this review and revision has been published[109].

5.7.2 Supporting evidence

The **ELV Directive** was mentioned by 4 respondents as potentially benefiting from the implementation of the essential use concept. One stakeholder in the targeted survey noted that exemptions under the ELV Directive can only be granted if there are no technically feasible alternatives which they suggest indicates that components of the essential use concept are already used in this Directive.

During a targeted interview, a business association argued that there was no need to implement the essential use concept in the ELV Directive as emissions of ELVs are already controlled appropriately and legally. For example, electric and electronic equipment waste must be handled according to WEEE Directive 2012/19/EU and Battery Directive 2006/66/EC. On the other hand, during the workshop an industry stakeholder highlighted that implementing the essential use concept in the ELV Directive could help increase its coherence and harmonisation with other legislation, namely RoHS.

5.7.3 Conclusion

The essential use concept could be used within Annex II such that exemptions to the restriction of lead, mercury, cadmium and hexavalent chromium in vehicles could be more universally defined and aligned better with other legislation.

The current terminology used in the ELV Directive refers to the uses of hazardous chemicals that are ‘unavoidable’. This term is not defined but could overlap with the criteria for essential use, in particular, a use may be considered unavoidable if there are no alternatives. It is unclear whether the Directive could consider uses which are not critical for the functioning of society or necessary for health and safety as ‘unavoidable’.

A horizontal essential use concept may lead to harmonised decisions across different sectors and also speed up decision making. As noted above, there is a consideration that this could, for example, lead to improved harmonisation between the ELV and RoHS Directives for regulating harmful chemicals.

It is noted that a crucial part of the assessment under ELV Directive is the stakeholder consultation, where economic operators and others may comment on alternatives. This should be an important consideration in the application of the essential use concept.

[108] European Commission. End of Life vehicles. Retrieved on 2022-11-23 at: https://environment.ec.europa.eu/topics/waste-and-recycling/end-life-vehicles_en
[109] European Commission. Have your say, End-of-life vehicles - revision of EU rules (public consultation). Retrieved 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12633-End-of-life-vehicles-revision-of-EU-rules/public-consultation_en

Part C

Essential use concept in REACH

6 Political and legal context with focus on REACH

Chemicals are integral for the well-being, high living standards and comfort of modern society. They are used in all economic sectors which include tangible goods, including health, energy, mobility, and housing. In this sense, they have and continue to enrich the lives of all EU citizens, and through further innovation continue to advance technology on an international scale. However, many chemicals have specific hazard properties that are particularly harmful for human health or the environment.

The European Green Deal[110], the European Union's growth strategy, has set the EU on a course to become a sustainable, climate neutral, and circular economy by 2050. It has also set a goal to better protect human health and the environment as part of an ambitious approach to tackle pollution from all sources and move towards a toxic-free environment.

If the Green Deal objectives are to be achieved, developments in chemical regulations and management will play a key role. As outlined, chemicals are ubiquitous in the environment, with some having hazard properties, and some causing harm to humans and/or the environment. The release of hazardous chemicals to the environment, as shown for example through water, soil, and biota monitoring data, as well as human biomonitoring data[111], is not aligned with the vision of a toxic-free environment, and therefore hinders the EU's zero pollution ambition. Furthermore, environmental emissions and the presence of harmful chemicals in materials and products impede the progression towards non-toxic material cycles and a circular economy (which would see waste and emissions eliminated). Action on chemicals is further warranted due to the expected rate of growth of the chemicals industry.

The European Commission published a CSS[112] on 14 October 2020. It was produced as part of the EU's zero pollution ambition, which is a key commitment of the European Green Deal. The strategy has three main goals to step up protection of humans and the environment from hazardous chemicals:

(1) Ensuring that all chemicals are used more safely and sustainably,

(2) Promoting that chemicals having a chronic effect for human health and the environment – substances of concern – are minimised and substituted as far as possible, and

(3) Phasing out the most harmful chemicals in uses non-essential for society, in particular in consumer products.

The CSS outlines a number of commitments by the Commission which will ensure coherence between chemicals legislation and the Green Deal. One of these commitments is to *"define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will*

[110] European Commission, (2022). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM(2019) 640.
[111] See outputs from the European Environment Agency/European Commission co-funded HBM4EU project
[112] European Commission, (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee And The Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM(2020) 667. 14th October 2020.

guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments."

The CSS has therefore put in place a plan for ambitious targets to work towards a vibrant and innovative chemicals industry without compromising human health and environmental protection. To this end, defining criteria for essential use will help maintain the effective function of REACH and the other legislation covered by the chemicals acquis in meeting these ambitions, leading to a more effective and preventative legal framework, and accelerating the phase out of the most harmful chemicals.

6.1 REACH

The Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) has been a central pillar of EU legislation for the assessment and management of chemicals since its adoption in 2007.

REACH puts in place the need for companies to demonstrate the safety of their chemicals, to ensure appropriate risk management and to communicate information on chemical properties, uses, and hazards through supply chains. REACH also puts in place additional mechanisms to identify and phase out/substitute chemical substances of very high concern (SVHCs[113]). The implementation of REACH has resulted in the creation and development of a public database[114] of detailed information on chemicals and their uses spanning 23,000 substances.

REACH is closely related and inter-linked with the Regulation on classification, labelling and packaging of substances and mixtures (CLP[115]), which covers the details of hazard identification and hazard communication. These two pieces of legislation cover much of the chemical manufacture, trade and use in the EU.

Through the support of EU industry (as REACH registrants), Member State Competent Authorities (MSCAs) and Commission services, REACH has over the last 15 years advanced the approach to how chemicals are assessed and managed, including elevating global approaches to chemical risk. REACH represents the highest standards in meeting the challenges of chemical identification, hazard assessment and risk management.

The 2018 REACH review[116] concluded that REACH is effective in delivering on its objectives in line with the above observations, however, it also noted there are opportunities for further improvement, for example, related to improving the efficiency of the restriction process to sufficiently protect consumers and professional users against risks from the most hazardous substances

There is no explicit or implicit reference to the essential use concept under REACH, but some components are reflected in the current authorisation and restriction provisions, to a limited extent, in terms of socio-economic analysis (SEA) and, to a greater extent, in terms of analysis of alternatives. Currently, multiple studies are underway to support the wider impact assessment for the revision of the REACH Regulation itself[117], including the implementation of the 'essential use'

[113] European Chemicals Agency, ECHA . Substances of very high concern identification. Retrieved on 2022-11-23 at: https://www.echa.europa.eu/substances-of-very-high-concern-identification

[114] European Chemicals Agency, ECHA. Dissemination Platform Reach - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation, Registered Substances Factsheets. Retrieved on 2022-11-23 at: https://echa.europa.eu/da/information-on-chemicals/registered-substances

[115] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

[116] European Commission, (2018). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the operation of REACH and review of certain elements, Conclusions and Actions. SWD(2018) 58 final. 5th March 2018.

[117] An overview of the planned activities, including Terms of References for the various contracts, contractors, information on the progress of the studies, where available relevant study reports and planned consultations is available via CIRCABC (CARACAL documents).

concept as part of the reform of authorisation and restriction, as well as other issues. Therefore, this part of the report is presented in the context of that wider impact assessment.

6.2 The wider EU chemicals 'acquis'

In order to effectively manage the risks posed by hazardous chemicals, the EU already makes use of sophisticated chemical laws (termed the chemicals acquis[118]). While REACH and CLP are core parts of the chemicals' acquis, there are many additional related and connected pieces of legislation to address specific issues relating to chemicals management (e.g. protection of consumers, prevention of chemical accidents, protection of workers etc).

Each EU legislative instrument relating to the management of chemicals considers, to some extent, how chemicals are utilised, what the key hazards are and sets in place mechanisms to deal with the issues of hazard and risk. The approach to these issues can of course vary depending on the specific piece of legislation and the overall aims of the legislation.

As the potential applications of chemicals are so broad and diverse, the policy landscape to manage all of these applications and potential related aspects is equally wide-ranging.

The concept of essential use has not yet been broadly applied to hazardous substances, but it has shown effectiveness in some specific pieces of legislation related to certain chemicals.

Some **related EU legislation** include an essential use concept or similar. For example, the Ozone Depleting Substances Regulation implements the concept of essential uses from the Montreal Protocol. Under the global agreement of the Montreal Protocol, Parties successfully phased out 98% of their ozone-depleting substances between 1989 and 2019.

The Biocidal Product Regulation 528/2012, for example, allows exemptions if it can be shown that the active substance is "essential to prevent or control a serious danger to human health, animal health or the environment" or if "not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance".

At the moment, there are no **national approaches** in place in EU Member States that apply the essential use concept on chemicals. Recently, legislators outside the EU have passed a law in Maine (US) to ban per- and polyfluoroalkyl substances in almost all products by 2030, except in cases of 'unavoidable use'.

6.3 Global context

As outlined in the UNEP (2019) Global Chemicals Outlook (GCO II)[119] report, the size of the global chemical industry exceeded USD 5 trillion in 2017 and is projected to double by 2030. It is also noted that global supply chains, and the trade of chemicals and products, are becoming increasingly complex, and that hazardous chemicals and other pollutants (e.g. plastic waste and pharmaceutical pollutants) continue to be released in large quantities. This demonstrates at a global level that further action to reduce the use and emissions of hazardous chemicals is required.

[118] No formal defined scope is identified for the chemicals' acquis, but broadly it can be assumed to span approximately 45 pieces of chemical and environmental legislation aimed at providing high levels of protection for human health and the environment, while maintaining the free circulation of substances on the internal market and enhancing competitiveness and innovation. See also the fitness check on the most relevant chemicals legislation

[119] United Nations Environment Programme, UNEP (2019). Global Chemicals Outlook II From Legacies to Innovative Solutions Synthesis report (2019). DTI/2230/GE.

Over the last 40 years, the international community has taken concerted action through multilateral treaties (as well as voluntary schemes) on some of the most harmful chemicals.[120] For example, the UNECE Convention on Long Range Transport of Air Pollution (CLRTAP) created the Aarhus Protocol on Persistent Organic Pollutants (POPs) in 1998 with the ultimate objective to eliminate any discharges, emissions and losses of POPs.[121] Further global commitments to protect human health and the environment from POPs were set in 2001 with the adoption of the UNEP Stockholm Convention[122].

However, it is also noted in the GCO II report that despite these global agreements reached, and significant action already taken, scientists continue to express concerns regarding the lack of progress towards the sound management of chemicals and waste. These include calls for systemic and transformational changes towards safer chemicals.

In 2006, the Strategic Approach to International Chemicals Management (SAICM)[123] was adopted by the first session of the International Conference on Chemicals Management (ICCM) as a multi- and cross-sectoral and participatory strategic approach. SAICM's overall objective is "to achieve the sound management of chemicals throughout their life cycle so that by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health". The ICCM, is currently conducting an intersessional period to develop the Strategic Approach and the sound management of chemicals and waste beyond 2020.[124]

The 2030 Agenda for Sustainable Development, including its 17 Sustainable Development Goals (SDGs)[125] and 169 targets, was adopted by the United Nations General Assembly in 2015. This included several targets specifically related to chemicals and waste management. For example, targets 3.9[126] and 12.4[127] and are of direct relevance for chemicals and waste management, however the sound management of chemicals and waste is also relevant for the achievement of many other SDGs.

The EU has potential to contribute significantly to the global need and ambition for safe management of chemicals. As one of the leading global chemical producers, with 14.4% of the global market in 2020[128], changes in EU chemical legislation have potential for far-reaching impacts. This is pertinent for REACH as the central piece of EU chemicals legislation (alongside CLP) which has inspired legislation in other countries (e.g. Korean REACH and UK REACH). Therefore, development and implementation of the essential use concept could have global significance.

[120] Examples include: Stockholm Convention on Persistent Organic Pollutants (POPs) (2004); Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (2004); Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1992); Montreal Protocol on Substances that Deplete the Ozone Layer (1989); Minamata Convention on Mercury (2017).
[121] United Nation Environment Programme, UNEP. Protocol on Persistent Organic Pollutants (POPs). Retrieved on 2022-11-23 at: https://leap.unep.org/content/treaty/protocol-persistent-organic-pollutants-pops#:~:text=The%20Executive%20Body%20adopted%20the%20Protocol%20on%20Persistent,eleven%20pesticides%2C%20two%20industrial%20chemicals%20and%20three%20by-products%2Fcontaminants.
[122] Secretariat of the Stockholm Convention
[123] United Nations Environment Programme, UNEP. Strategic Approach to International Chemicals Management. Retrieved on 2022-11-24 at: https://www.saicm.org/
[124] United Nations Environment Programme, UNEP. Strategic Approach to International Chemicals Management, Beyond 2020, Retrieved on 2022-11-24 at: https://www.saicm.org/Beyond2020/IntersessionalProcess/tabid/5500/language/en-US/Default.aspx
[125] United nations, UN. The Sustainable Development Goals. Retrieved on 2022-11-23 at: https://sdgs.un.org/goals
[126] Target 3.9: By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination.
[127] Target 12.4: By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.
[128] Cefic, (2022). 2022 Facts And Figures Of The European Chemical Industry. Retrieved on 2022-11-23 at: https://cefic.org/a-pillar-of-the-european-economy/facts-and-figures-of-the-european-chemical-industry/

7 Problem definition

7.1 Introduction

The 2018 review of the operation of the REACH Regulation concluded that the functioning of REACH has improved in response to the conclusions of the 2013 review and indicated that REACH is leading to the overall improved protection of human health and the environment and strengthening of the internal market.

However, the review also identified a number of persisting issues which currently limit the full delivery of benefits from REACH (e.g. to human health, the environment, and competitiveness and innovation) where further improvements are required. These issues are the basis for the problem definition for the overall revision of REACH, to which this project is intended to feed into.

For example, the 2018 REACH review highlights that the efficiency of the way that REACH deals with chemical risk needs to be improved, including simplification of the authorisation and restriction processes. More specifically, this identifies a need to clarify the requirements and make the process more predictable.

This section details the specific problem definition in relation to the potential application of the essential use concept in the context of improving the efficiency of REACH authorisation and restriction, focussing on the following two main issues, specifically:

- The REACH authorisation regulatory process is not efficient enough, decision-making is slow; it is burdensome and does not provide enough incentives for substitution; and
- The pace of restrictions is not sufficient, and inefficiencies delay the rate at which regulatory measures are implemented to address risks to human health and the environment and to ensure that the most harmful chemicals are adequately regulated.

7.2 The REACH authorisation process is not efficient enough, decision-making is slow and burdensome and does not provide enough incentives for substitution

As highlighted in the Commission's Inception Impact Assessment for the revision of REACH[129], the current REACH authorisation process is considered too 'heavy and inflexible' and 'overly complex, burdensome and slow, both for companies and authorities'.

Importantly, these limitations lead to in inefficiencies in regulation of the most harmful chemicals, leading to delays in risk management measures to protect human health and the environment. Indeed, it is noted from the 2018 REACH review that industry stakeholders consider *"the mechanisms to address risks through regulatory measures, namely authorisation and restriction, are excessively burdensome and lengthy, leading to slow progress to substitute and phase-out hazardous chemicals"*.

REACH authorisations for uses in the Annex XIV substances can be granted based on one of two possible routes:

[129] European Commission, (2022). Have your say, revision of REACH Regulation to help achieve a toxic-free environment - Inception Impact Assessment. Retrieved on 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en

i) **Adequate control route**: by demonstrating that the risk from using the substance is adequately controlled, i.e., that the exposure is below the derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) (Article 60(2) of REACH); and

ii) **Socio-economic route (SEA route):** by demonstrating that the socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies for the applicant (Article 60(4) of REACH). The demonstration of socio-economic benefits is a legally required component for consideration in decision-making and most of the applicants provide evidence for this legal criterion through a socio-economic analysis, although this is not a mandatory part of the application for authorisation.

As it currently stands in REACH, the "benefits" considered in the SEA route of authorisation are very broadly defined. For example, Annex XVI states that, among other aspects, the SEA may include impacts of a granted or refused authorisation on consumers and social implications, as well as any other issue considered to be relevant by the applicant(s). This may allow authorisations to be granted where the benefits from use emanate from essentiality (i.e. necessity for health, safety or criticality for the functioning of society), but also for uses which are not essential for society but have other benefits (e.g. economic benefits).

ECHA suggests that the SEA process weighs up the pros and cons of an action for 'society as a whole'[130], a broad umbrella statement which could theoretically include consideration of 'criticality for the functioning of society' or 'necessity for health and safety' in order to strengthen the justification, among other socio-economic benefits which may not relate to criticality for the functioning of society or necessity for health/safety. Feedback from Commission experts as part of this project[131] indicates that 'wider societal considerations' (e.g. potentially relating to health and safety or functioning of society), are rarely considered in detail and quantitatively.

The assessment of alternatives in the SEA route is not simple as there are still questions on what is meant by acceptability of alternatives in the context of the assessment carried out as part of the authorisation process. This can make the process burdensome and unpredictable for industry applicants. The analysis of alternatives under REACH includes consideration of technical and economic feasibility for the applicant and downstream users. In practice, this can be a significant undertaking in terms of time and cost burden for applicants.

Moreover, it has been argued that the approach to alternatives assessment in the current authorisation provision under REACH may not adequately encourage the phase out of the most harmful chemicals. It is noted from the 2018 REACH review that: "*NGOs, consumer associations, and some public authorities, argued that the practice of granting all authorisations, even when alternatives exist, was disadvantaging companies who have invested in safer alternatives and not incentivising enough the substitution of hazardous substances*". Furthermore, although inclusion of a substance in the authorisation list is a significant driver for substitution[132], once an authorisation has been granted (especially with a long review period), it could be argued that there is lower incentive for companies to intensify their work on substitution.

Regarding applications for authorisation in general, the 2018 REACH review[133] reported concerns raised by several Member States, NGO stakeholders and the European Parliament as to the quality of specific applications covering a large number of companies, which can hamper the ability of the Committees to assess them. One specific concern related to a broad description of the uses applied for in cases where the substance is used in many different types of articles (one example

[130] European Chemical Agency, ECHA. Socio-economic analysis in REACH. Retrieved on 2022-11-23 at: https://echa.europa.eu/da/support/socio-economic-analysis-in-reach

[131] Based on discussions with Commission experts as part of Task 2 data gathering for this project. A full presentation of results from Task 2 data gathering on REACH was presented in the interim report prepared as part of this project.

[132] European Chemicals Agency, ECHA (2020). Impacts of REACH restriction and authorisation on substitution in the EU. ECHA-20-R-09-EN. July 2020.

[133] Annex 5 of the review.

noted was the use as a plasticiser in polymers or as pigment in paints, which are then used in the production of many different types of articles) thereby rendering the analysis of alternatives for the entire scope of the uses applied for more challenging.

As of April 2022, 248 applications for authorisation were received by ECHA from 396 applicants, covering 382 uses.[134] The majority of all applications were for two substances: chromium trioxide (66 applications) and octyl- (OPE) and nonylphenol ethoxylates (NPE) (67 applications). Many of the applied for uses were similar and therefore resulted in duplication of efforts by both industry (in applications) and authorities (in assessments), which is a key source of the perceived inefficiency in the process.

It is noted in the Commission's Inception Impact Assessment that "*a multitude of applications for the use of small quantities of substances, unclear criteria for authorisation and information gaps (in particular for uses where competitors 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*".

The delays and/or inefficiencies in the authorisation process can translate into overly burdensome time and cost requirements for applicants. Authorisation application costs are approximately €180 000 per use (excluding fees), reflecting total application costs of approximately €9 million annually.[135] Without intervention, overly burdensome time and cost inputs for industry could persist under the current authorisation system over the next 30 years.

The burden of authorisation is partly driven by unclear criteria for the authorisation process, in particular, regarding the lack of suitable alternatives. For instance, the judgment of the General Court (GC) in case T-837/16 Sweden vs. Commission[136] annulled the Commission's 2016 decision granting an authorisation for certain uses of lead sulfochromate yellow and lead chromate molybdate sulphate red under the SEA route of Article 60(4) of REACH. The GC concluded that the EU Commission infringed REACH by authorising the lead chromates without having duly examined and established the unavailability of suitable alternatives[137]. This court case led the Commission to request additional information also for other applications, in order to determine whether there were suitable alternatives in general and a substitution plan was required, creating delays and additional administrative costs for both companies and authorities.

The 2018 REACH review[138] highlighted that the authorisation process is perceived by companies as having a marked impact on competitiveness, innovation and investment decisions. More specifically, the continuous process of including substances into Annex XIV is considered by industry to create regulatory uncertainty for the use of substances, that could in some cases be critical to some industrial processes or applications.

The 2018 REACH review highlighted that "*ongoing efforts to streamline and simplify the authorisation process should continue with a view to clarifying the requirements and make the process more predictable",* noting in particular the need to focus attention on cases where the applications are to cover many different operators or their uses serve further businesses in the supply chain, ultimately making the process work more efficiently and, in turn, will make it less controversial to subject new substances to it in the future.

[134] European Chemicals Agency, ECHA (2022). Statistics on received applications for authorisation and review reports. Retrieved on 2022-11-23 at: Statistics on received applications for authorisation and review reports - ECHA (europa.eu)
[135] Eftec et al. (2017). Impacts of REACH Authorisation.
[136] Case T-837/16: Judgment of the General Court of 7 March 2019 — Sweden v Commission (REACH — Commission decision authorising the use of lead sulfochromate yellow and of lead chromate molybdate sulfate red — Article 60(4) and (5) of Regulation (EC) No 1907/2006 — Consideration of the unavailability of alternatives — Error in law)
[137] Ashurst, EU Court sides with Sweden and annuls REACH authorisation for lead chromates
[138] Annex 5 of the review

The issues discussed above are key factors impacting the overall effectiveness and efficiency of the REACH authorisation process and preventing the key objectives of REACH from being met. This highlights the potential need to revise the criteria used to assess REACH authorisations to make the process more effective and efficient, both for industry (for example relating to the overall burden, costs and predictability) and the overall protection of human health and the environment (for example relating to the phase out of the most harmful chemicals and the substitution to safer alternatives).

7.3 The pace of restrictions is not sufficient

The 2018 REACH review highlighted that the preparation of Annex XV Dossiers is still perceived as an excessive burden by Member States, due in part as well to the lack of specific expertise, namely on socio economic assessment, the costs associated to their preparation and the high number of requests for additional information from ECHA committees. It was specifically recommended to assess the possibilities to improve efficiency in the implementation of the restriction processes in accordance with Articles 68 and 69.

Under REACH Article 68(1), restriction proposals include socio-economic analysis examining the costs and benefits of a proposed restriction. This is a required section of Annex XV restriction reports to support the Commission decision. Article 69(6)b invites all interested parties to submit a socio-economic analysis, or information which can contribute to one of the suggested restrictions, examining the advantages and drawbacks of restrictions (in response to the publication of the dossier).

The restriction process through specific risk assessment is considered to put a high burden on authorities to document unacceptable risk for health or the environment.[139] The high burden associated with restrictions slows down the rate at which restrictions can be implemented, therefore delaying protection of human health and the environment against risks from chemicals. For example, it can take approximately three years for restriction proposals to result in a restriction in Annex XVII of REACH.[140]

The Commission's Inception Impact Assessment noted that the current restriction process "is too slow to sufficiently protect consumers and professional users against risks from the most hazardous substances". In terms of ensuring adequate protection of human health and the environment, it was noted that "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 reprotoxic (CMR) substances in consumer products, this process cannot be used for other critical hazard classes including endocrine disruptors, persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB) substances, immunotoxicants, neurotoxicants, respiratory sensitisers or substances that affect specific organs".

While the high burden is a problem for human health and environmental protection as it slows down the pace at which harmful substances are restricted (described below in section 7.4), it also presents an economic problem as the burden is expected to translate to relatively high costs to industry. Furthermore, there are huge variations in costs between individual cases. ECHA estimates place the expected cost to industry per restriction between 2010 and 2020 in the EU at

[139] European Commission, (2022). Have your say, revision of REACH Regulation to help achieve a toxic-free environment - Inception Impact Assessment. Retrieved on 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en

[140] For example: Commission Regulation (EU) 2020/1149 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates; Commission Regulation (EU) 2018/589 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards methanol.

between €0 and €955 million per year. The median cost is €6 million, and the mean cost is €53.3 million per restriction per year[141].

7.4 Consequences of these problems

The key problems associated with the restriction and authorisation provisions under REACH (detailed in the two sections above) are significant economically, socially, and environmentally.

As discussed in the two sections above, the current approach taken for authorisation and restriction under REACH is broadly based on the comparison of risks and benefits (in most cases demonstrated through the SEA). This is perceived to be highly complex, inefficient and resource-intensive and leads to slow, long and complex decision-making.

The inefficiencies highlighted above are expected to manifest themselves as overly burdensome cost and resource inputs for industry as well as authorities. It is also noted that these costs could potentially persist or increase in future years (depending on the number and complexity of the proposals for authorisation or restriction).

Therefore, a key problem to be addressed is the lack of effective criteria for assessing authorisations and derogations from restrictions so that the application and decision-making process is made more effective, efficient, and predictable.

In addition, risks to human health and the environment from the most harmful chemicals are being increasingly realised, for example, the EEA (2019) predicted deteriorating trends in chemical pollution and risks to human health, well-being, and ecosystems up to 2030.[142] The most harmful chemicals include endocrine disruptors (which may cause childhood obesity, male infertility, endometriosis, diabetes, etc.), neurotoxicants (which may cause Alzheimers disease etc.), immunotoxicants (which may cause multiple scelorosis etc.), and carcinogens (which may cause occupational cancer etc.). The problem is not quantified for all of the most harmful chemicals under the scope of REACH, but can be exemplified by a few cases of specific chemicals (already regulated due to severe health implications) where health impacts across the EU have been estimated to cause billions of euros of costs annually.[143] Furthermore, environmental risks are increasingly demonstrated by monitoring and modelling data, for example, several REACH-registered chemicals, including mercury, brominated diphenyl ethers, cadmium, nickel, and bis(2-ethylhexyl) phthalate, were responsible for a number of failures to achieve good chemical status in EU surface waters in 2018.[144]

[141] European Chemical Agency, ECHA (2021). Costs and benefits of REACH restrictions proposed between 2016-2020. ECHA-21-R-02-EN. February 2021.
[142] European Environment Agency, EEA (2019). The European environment —state and outlook 2020, Knowledge for transition to a sustainable Europe.
[143] For example, €10 billion costs from PBDEs due to IQ loss and intellectual disability (Trasande, et al. (2016). Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis. Andrology, 4(4), 565–572); €47 billion costs from lead and methylmercury (Amec Foster Wheeler et al. (2017) Study on the cumulative health and environmental benefits of chemical legislation. European Commission DG Environment)
[144] European Environment Agency, EEA (2018). European waters assessment of status and pressures 2018. No 7/2018

8 Why should the EU act?

8.1 Introduction

This section provides further details to expand upon the problem definition of why action is needed at European Union level (as opposed to individual Member States). This section has further been disaggregated into two key components: firstly, on the legal basis for why EU level action is warranted, and secondly, in terms of subsidiarity, i.e., why the problems must be addressed at an EU level rather than national level.

8.2 Legal basis

The Treaty on the Functioning of the European Union (TFEU) provides the basis for action at EU level. Specifically, this relates to Article 114, which establishes the following:

- Article 114(1): EU competence to "*adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market*", i.e., the adoption of legislation to ensure the free flow of substances, mixtures, and articles within the European Union.
- Article 114(3): "*The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.*" i.e., the adoption of legislation to ensure environmental and consumer protection.

Article 11 of the TFEU also sets out that "*environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development*". The intervention also takes into account other relevant provisions of the TFEU, i.e., Titles XIV on Public Health, XV on Consumer Protection and XX on Environment. Furthermore, Article 4(2) of the TFEU provides the EU has shared competence in the policy areas of internal market, environment, consumer protection and common safety concerns in public health matters.

Specifically in terms of REACH, the ongoing revision, guided by the findings of the 2018 REACH Evaluation, is the basis for intervention.

8.3 Subsidiarity

The principle of subsidiarity requires that the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States but can be better achieved at Union level. For the problems identified in section 7 of this report, a case can be made that EU action on the essential use concept is warranted under subsidiarity, both in terms of the necessity to intervene at EU level and the added value of EU rather than Member State intervention. This is illustrated with the following points:

- The EU operates as a single market allowing the free movement of goods (including chemicals, as well as articles and products containing chemicals) between Member States. Without common rules for producing and using chemicals, the free circulation of goods on the internal market would be undermined, as companies would need to adapt their products to national rules. This would introduce additional administrative

burden and practical challenges, as well as complexities in enforcement, and negative impacts on the level playing field between companies based in the different Member States.

- The chemicals acquis already applies at EU level. Developing and implementing criteria for an essential use concept at a national level would therefore require an entire restructuring of the chemical regulatory landscape, as restrictions and authorisations under REACH are applicable across the EU, not at a Member State level.
- The problems identified in section 7 are transboundary and widespread as they affect all Member States. Chemicals and chemical products are produced, supplied and used in all Member States. The free movement of goods between Member States and the potential of some chemicals for long range transport in the environment means that chemicals produced in one Member States may result in human and environmental risks in other Member States. Therefore, national level action would be insufficient.

Overall, EU, rather than Member State, action would be most coherent with the current regulatory landscape (as the decision-making on restrictions and authorisations of the most harmful chemicals is already an EU, not Member State, competence) and allow the transboundary problems associated with chemicals to be addressed in a transparent and uniform way across Member States, bringing predictability for industry and regulators. In addition to being necessary, action at EU level would bring added value as it could help the EU retain its position as a global frontrunner in the regulation of chemicals, for example, setting an example for other countries to follow, which would bring benefits for the wider supply chain (intra-extra-EU). EU action could also positively contribute to the United Nations Sustainable Development Goals (SDGs) (e.g. addressing risks from chemicals is imperative to achieve SDG #3 on good health and well-being, as well as SDG #6 on clean water and sanitation, among others). Finally, EU action is important to uphold the EU's aims related to environmental protection, well-being of citizens, and the internal market.[145]

[145] European Union. Aims and values. Retrieved on 2022-11-23 at: https://european-union.europa.eu/principles-countries-history/principles-and-values/aims-and-values_en

9 Objectives of the intervention

The overall aim of implementing the essential use concept in REACH is to allow systematic decision-making to facilitate the phasing out of the most harmful chemicals by only allowing them when their use is essential for society, i.e., necessary for health/safety or critical for the functioning of society and where there are no alternatives acceptable from the standpoint of the environment and health (as elaborated in Part B of this report).

In practice, it is envisaged that the essential use concept within generic and specific risk management approaches can provide a tool for progressive phasing out of the most harmful chemicals, primarily in non-essential uses and ultimately in essential uses. The concept is intended to prevent the use of the most harmful chemicals for non-essential uses by changing the approach for justifying exemptions from restrictions and justifying the granting of authorisations. Furthermore, the concept is intended to minimise essential uses, as well as their associated exposure and risks to human health and the environment as far as possible. Lastly, the concept is intended to encourage substitution of essential uses by requiring industry to demonstrate that appropriate effort is being made to substitute essential uses.

The essential use concept is intended to bring more simplicity, transparency, predictability and efficiency in authorisation decisions and derogations from restrictions, by replacing or complementing (depending on the various policy options) the current rationale used to justify derogations from restrictions and the granting authorisations, with clear criteria for essential use. These improvements are intended to speed up decision-making, therefore increasing the rate of restrictions of the most harmful chemicals so that risks to human health and the environment can be addressed as efficiently as possible, without the delays caused by the complexities in the current processes.

In addition to environmental and health benefits, improving the simplicity and predictability of authorisation and restriction is intended to make the processes easier and faster for both industry and authorities, therefore saving time and resources.

By increasing the strictness of criteria for derogations, the essential use concept is intended to encourage innovation in safe and sustainable chemicals and materials to be used as alternatives to the most harmful chemicals.

10 Policy options for REACH

This chapter provides the following elements, in alignment with the Better Regulation Toolbox (tool #16 on how to identify policy options):

- An overview of the baseline;
- An overview of alternative policy sub-options for the essential use concept within (the reform of) authorisation and restriction;
- A viability screening of sub-options; and
- A description of the sub-options in greater depth (including common features and additional parameters).

10.1 Introduction

Based on the REACH Review from 2018[146], the CSS announced a **targeted revision of the REACH regulation, including the extension of the generic risk management approach (enshrined in REACH, Article 68(2)) to further hazard classes and uses, a reform of the REACH authorisation and restriction provisions, and the definition of essential use criteria,** the latter to be applied in all relevant EU legislation for both generic and specific risk assessments.

The implementation of the essential use concept in REACH is to be considered in the context of the reform of REACH authorisations and restrictions. Where implemented, the essential use concept can ensure that only essential uses of the most harmful chemicals are allowed. The intention would be to increase efficiency and predictability and to simplify and speed up the decision-making (see objectives section 9). Therefore, in this section, we set out various sub-options for the essential use concept (within the main options for authorisation and restriction being assessed under a separate study[147]) to inform the decisions on authorisations and derogations from restrictions. In particular, this means that regardless of the final choice of option for the revision of the authorisation and restriction provisions under REACH, the present project assesses whether the essential use concept and criteria would be beneficial if used for decisions on applications for authorisation or for derogations from restrictions.

The study on the extension of the use of the generic risk management approach to further hazard classes and uses and to reform the REACH authorisation and restriction proposes policy options for how to reform the REACH authorisation and restriction provisions, as follows[148]:

- **Policy option 0: Do nothing (baseline)**.
- **Policy option 1**: **Streamline and keep separate the authorisation and restriction provisions –** The use of substances on Annex XIV and their presence in articles is subject to an authorisation given to applicant, and applying only to the applicant and, if appropriate, an immediate actor up the supply chain or downstream users.

[146] The 2018 REACH Review concluded that REACH is effective, but that there are opportunities for further improvement, simplification, and burden reduction. In its conclusions, the review identified a number of actions to improve the implementation of REACH, including on authorisation and restriction.
[147] VVA (Unpublished) 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: Impact Assessment, Third Draft Final Report [06/09/2022]
[148] We are aware that these options are currently being revised by the contractor based on comments from the Commission which were provided to us. We will work with the contractor and aim to assess the sub-options for the essential use concept within the latest update of the options on authorisation and restriction.

- **Policy option 2**: **Merge authorisation and restriction provisions into one system –** The possibilities for derogations from restrictions/authorisation requirements would be aligned into one common system for restrictions (including for listed SVHCs, after integration of ex-Annex XIV into Annex XVII), with three different possibilities:
  - Authority-driven derogations, already included in the restriction decision (same as in the baseline);
  - Industry-driven derogations of general applicability (new element), i.e., the derogation is applicable to all uses, not only the specific applicants, when the restriction decision allows for their submission.
  - Industry-driven authorisations of individual applicability, i.e., applicable only to the specific applicants, when the restriction decision allows applications. This would, however, remain exceptional and be discouraged by strict requirements compared to industry-driven derogations of general applicability.
- **Policy option 3: Abandon the authorisation provisions, but keep the candidate list –** There will be no more inclusion of SVHCs in Annex XIV and this Annex will be phased out and eventually repealed. The use of a substance covered by a restriction in Annex XVII (based on Article 68(1) or 68(2)) is only possible if a derogating provision is included in the restriction.

The table below provides an overview of where the essential use concept could be implemented in the current reform for authorisation and restriction depending on options for authorisation and derogations of restrictions (i.e., the three options above and the baseline).

Table 10.1 Essential use within options for the reform of authorisation and restriction

Reform of authorisation, restriction and GRA		Where the essential use concept (ESU for brevity in this table) can fit into the options for the reform of authorisation, restriction and GRA			
Type of ban (Authorisation / Restriction)	**Type of derogation (application for authorisation or derogation from restriction)**	**ESU in Baseline**	**ESU in Option 1**	**ESU in Option 2**	**ESU in Option 3**
Authorisation	**Application for authorisation (valid only for individual applicant-s)**	◆	◆		
Restriction 68(1)	**Authority-driven derogation of general applicability to all users**	◆	◆	◆	◆
	Industry-driven derogation of general applicability to all users			◆	
	Industry-driven authorisation of individual applicability			◆	
Restriction 68(2), i.e., GRA	**Authority-driven derogation of general applicability to all users**	◆	◆	◆	◆
	Industry-driven derogation of general applicability to all users			◆	
	Industry-driven authorisation of individual applicability			◆	

** Option 2 would introduce the possibility for "authorisations" of substances restricted under Article 68. These "authorisations" would represent a type of derogation from restriction.*

10.2 Baseline

Sub-options to introduce the essential use concept in REACH include a baseline as the 'no-policy-change' scenario, including relevant EU-level and national policies in force. Under the baseline:

- This is a **no-policy change** scenario, and the essential use concept would not be introduced.
- **The current situation and EU regulatory framework**: currently, REACH includes two titles for prohibiting or setting conditions for the use of certain substances : first, restrictions (Title VIII) which enable the EU to impose bans or conditions on the manufacturing, placing on the market or use of substances; and second, a ban upon uses of substances listed in Annex XIV unless their use is authorised (Title VII), which ensures that risks from substances of very high concern are properly controlled while they are progressively replaced by suitable alternatives.
- There are no **national approaches** in place in the EU already regarding the application of the essential use concept to chemicals. It is worth noting though that,

recently, legislators have passed a law in Maine (US) to ban per- and polyfluoroalkyl substances in almost all products by 2030, except in cases of 'unavoidable use'.[149]

- Some **related EU legislation** include an essential use concept or similar. These are further elaborated Part B of this report.
  - For example, the Ozone Depleting Substances Regulation implements the essential use concept from the Montreal Protocol.
  - There is no explicit or implicit reference to the essential use concept under REACH, but some components are reflected in the current authorisation and restriction provisions: i.e., to a limited extent, in some parts of socio-economic analysis and, to a greater extent, in terms of analysis of alternatives.
- **How is the situation expected to evolve?**
  - The applicable legislation in terms of risk management of chemicals will continue to be REACH (alongside other pieces of legislation in the chemicals acquis, e.g. product-specific legislation). As part of the overall revision of REACH, both the authorisation and restriction provisions may be reformed, depending on the preferred option taken forward for those two provisions. This revision may include clarifications and simplifications of the current provisions, integrating the authorisation and restriction systems into one, extending the generic risk approach to restrictions on additional hazard classes and uses, etc.
  - Without introducing the essential use concept in REACH, it is expected that the current provisions and processes to decide whether to grant authorisations and implement derogations from restrictions would continue. Under the options for the reform of authorisation and restriction, these would be implemented in the relevant provisions (Table 10.1 above). Some non-essential uses of the most harmful chemicals would be expected to continue (e.g. those where socio-economic benefits outweigh risks and there are no alternatives available). In addition, a number of practical challenges and concerns (identified in the REACH review 2018) related to authorisation and restriction may persist in the absence of the essential use concept (e.g. contributing to a heavy and burdensome authorisation process and a slow restriction process). Nevertheless, the concept and criteria may serve informally to guide certain considerations by authorities. For example, it was recently announced that the essential use concept, which was initially to be incorporated in a restriction proposal (led by five European countries) to ban all per- and polyfluoroalkyl substances in the EU, will not be used to justify possible exclusions in the restriction proposals. The reason was not to hamper the timing and advancement of the restriction proposal and interfere with the ongoing development of the essential use criteria and discussions over their introduction in REACH.[150] The essential use concept was also considered during the proposal for granting an authorisation for some uses of alkylphenol ethoxylates, however, the concept was not used as an additional justification for similar reasons.

[149] Maine Department of Environmental Protection, (2022). PFAS in Products, Maine Department of Environmental Protection. Retrieved on 2022-11-23 at: https://www1.maine.gov/dep/spills/topics/pfas/PFAS-products/index.html
[150] Chemical Watch, (2022), EU PFAS proposal will not incorporate 'essential use'. Retrieved on 2022-11-23 at: https://chemicalwatch.com/447571/eu-pfas-restriction-proposal-will-not-incorporate-essential-use

10.3 Alternative policy sub-options

The sub-options to address the problems identified in section 7 have followed the guidance set out in the Better Regulation Toolbox (BRT) #16[151]. This stage is intended to identify as many relevant policy responses as possible within the political constraints and scope of the initiative. In the context of the current project, this is limited to the targeted revision of the REACH regulation and in particular, the reform of the authorisation and restriction provisions.

The aim here has been to consider a range of sub-options within this context, from the less intrusive to the more interventionist. As per the BRT, consideration has been given to different levels of option aggregation (sub-options, alternative detailed parameters, implementation modes, etc.). We have therefore set out both **'sub-options'** and **alternative parameters**. In addition to the **baseline**, the following sub-options are considered for the essential use concept:

- **Sub-option A**: Non-binding guidance for the introduction of the essential use concept in authorisation and restriction, as an optional consideration, complementary to current provisions.
- **Sub-option B**: Binding implementing regulation and supporting guidance for the introduction of the essential use concept in authorisation and restriction, as an optional consideration, complementary to current provisions.
- **Sub-option C**: Introduction of legal changes in REACH for essential use under authorisation and restriction, with the **essential use concept being a complementary approach to the socio-economic (SEA) route and adequate control route** (ACR) to decide on authorisations. The essential use concept would be used to decide on all derogations from restrictions.
- **Sub-option D**: Introduction of legal changes in REACH for essential use under authorisation and restriction, with the **essential use concept replacing the socio-economic route** as an approach to decide on authorisations and derogations from restriction. In addition, the **adequate control route for authorisation would be removed,** so that all applications for authorisation and derogations from restriction would be based on the essential use concept.

Within the above sub-options, the parameters below are also considered (and further described in section 10.5.6):

- Initial rapid screening for alternative products or services available on the market in the same category;
- Initial rapid screening of criticality for the functioning of society and necessity for health/safety;
- Fall-back mechanisms for emergency and crisis situations.

[151] As per Tool #16 of the Better Regulation Toolbox, there are four suggested steps in order to identify a realistic set of options:
(1) Construct a baseline from which the impacts of the policy options will be assessed.
(2) Start by compiling a wide range of alternative policy options.
(3) Identify the most viable options; explain the discarded policy options.
(4) Describe in reasonable detail the key aspects of the retained policy options to allow an in-depth analysis of the associated impacts.

The table below shows how each sub-option for the essential use concept could be implemented in the various types of applications for authorisation and restriction derogations within the reform for authorisation and restriction.

Table 10.2 Sub-options for essential use concept within each provision and by type of derogation

Reform of authorisation, restriction and GRA			How could the essential use concept (referred to as ESU in this table for the sake of brevity) be implemented in justifying the derogation / authorisation in each option?			
Type of ban (Inclusion in Annex XIV / Restriction)	**Type of derogation (application for authorisation or derogation from restriction)**	**Options (from VVA study) in which derogation is applicable**	**Sub-option A Guidance document**	**Sub-option B Implementing act**	**Sub-option C Legal changes to REACH (adequate control route, ESU within SEA route)**	**Sub-option D Legal changes to REACH (remove ACR and SEA routes, only ESU)**
Inclusion in Annex XIV	**Application for authorisation (valid only for individual applicant-s)**	Baseline 1	ESU can be used to inform the duration of the time-limited review period for authorisations granted via the adequate control route or the socio-economic route (e.g. to set a shorter review period for non-essential uses) – non-binding, but available to the European Commission. Authorisations may be granted via the existing adequate control route, or, if an authorisation cannot be granted following the adequate control route, ESU can be used for assessing authorisation applications within the socio-economic	ESU can be used to inform the duration of the time-limited review period for authorisations granted via the adequate control route or the socio-economic route (e.g. to set a shorter review period for non-essential uses – binding. Authorisations may be granted via the existing adequate control route, or, if an authorisation cannot be granted following the adequate control route, ESU can be used for assessing authorisation applications within the socio-economic	ESU can be used to inform the duration of the time-limited review period for authorisations granted via the adequate control route or the socio-economic route (e.g. to set a shorter review period for non-essential uses – binding. If an authorisation cannot be granted following the adequate control route, ESU can be used for assessing authorisation applications within the socio-economic route - binding.	Removal of adequate control route and SEA routes. ESU to be used for assessing authorisations– binding.

			route (to decide whether to grant an authorisation) – non-binding, but available to industry and the European Commission.	route (to decide whether to grant an authorisation) – binding.		
Restriction 68(1)	**Authority-driven derogation of general applicability to all users**	Baseline 1 2 3	ESU can be implemented by authorities to scope the restriction (e.g. defining uses not covered by the restriction proposal).	Same as sub-option A.	ESU to be used to propose derogations from restrictions as part of the restriction proposal. ESU to be implemented by authorities to scope the restriction (e.g. defining uses not covered by the restriction proposal).	Same as sub-option C
	Industry-driven derogation of general applicability to all users	2	ESU can be used for derogation requests of general applicability, where these are allowed in the restriction.	Same as sub-option A.	ESU to be used for derogation requests of general applicability, where these are allowed in the restriction	Same as sub-option C
	Industry-driven authorisation of individual applicability	2	ESU can be used for applicant-specific derogations, where these are allowed in the restriction.	Same as sub-option A.	ESU to be used for applicant-specific derogations, where these are allowed in the restriction	Same as sub-option C.
Restriction 68(2) GRA	**Authority-driven derogation of general applicability to all users**	Baseline 1 2 3	ESU can be used to propose derogations from restrictions as part of the restriction proposal. ESU can	Same as sub-option A.	ESU to be used to propose derogations from restrictions as part of the restriction	Same as sub-option C.

			be implemented by authorities to scope the restriction (e.g. defining uses not covered by the restriction proposal).		proposal. ESU to be implemented by authorities to scope the restriction (e.g. defining uses not covered by the restriction proposal).	
	Industry-driven derogation of general applicability to all users	2	ESU can be used for derogation requests after the restriction is adopted, where allowed in the restriction.	Same as sub-option A.	ESU to be used for derogation requests of general applicability, where these are allowed in the restriction	Same as sub-option C.
	Industry-driven authorisation of individual applicability	2	ESU can be used for derogation requests after the restriction is adopted, where allowed in the restriction.	Same as sub-option A.	ESU to be used for applicant-specific derogations, where these are allowed in the restriction.	Same as sub-option C.

10.4 Screening of sub-options

According to the BRT (tool #16), a number of different parameters should be considered when screening policy (sub-)options. These include:

- Legal feasibility, including competence of the EU to act, and existing legal obligations.
- Technical feasibility and whether there are any relevant constraints in implementation, monitoring, or enforcement.
- Previous policy choices, which may rule out considering previously discarded (sub-) options again.
- Coherence with other EU policy objectives and sustainable development goals.
- Effectiveness and efficiency, i.e., if it is clear at an early stage that certain (sub-) options would have a worse cost-benefit balance.
- Proportionality.
- Political feasibility, and whether to discard (sub-)options that would fail to garner the necessary political support.
- Relevance and whether the (sub-)options address the needs of the policy intervention
- Identifiability, and whether to discard options that are not materially different from other (sub-)options being considered.

The table below includes a number of considerations against the different (sub-)options.

Table 10.3 Screening of sub-options

Screening criteria	Screening of sub-options
Legal feasibility	**Sub-option A** The essential use concept would be introduced through guidance, which would not require any legal changes to the enacting terms of REACH. For restriction, introduction of the essential use concept through guidance would be legally feasible because the essentiality of a substance for society can, in principle, already be taken into account, e.g. to consider whether to propose a derogation from the restriction, by the Commission, ECHA or the Member State when preparing a restriction proposal, under both Article 68(1) and Article 68(2). Such consideration of the essential use concept would however only be a possibility left to the discretion of the authority who is also responsible to justify the derogation. Under Article 60(4) on the socio-economic route to authorisation, an authorisation may only be granted if: **a)** it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, and **b)** if there are no suitable alternative substances or technologies. This means that the Commission has broad discretion on whether to grant an authorisation subject to two minimum conditions. The Commission's decision on whether any of these two conditions are met is not limited to only taking into account the scientific opinions of RAC and SEAC. This decision may include elements that go beyond quantitative and qualitative scientific assessment and may take into account a broader overall balancing of interests of a social, economic, policy or moral nature. In addition, Annex XVI (defining elements that may be included in an SEA) notes that "an SEA may also address any other

Screening criteria	Screening of sub-options
	issue that is considered to be relevant by the applicant(s) or interested party". The possibility to take into account essential use-related aspects can therefore be included in the range of elements that the Commission may consider. Furthermore, where those conditions are met, under Article 60(4) the Commission has broad discretion to grant an authorisation ('may') and may therefore consider e.g. any legitimate and proportionate political or public interest issues in order to grant or not to grant an authorisation in each case. In principle, it is possible to take into account whether the use of a substance is essential for society or not, although this has not yet been done in practice. Should this be the case, the Commission would need to explain how the essential use aspects have been taken into account and provide reasons as part of the justification for its decision, in line with the criteria of Article 60(4). Under Article 60(2) on the adequate control route, an authorisation must be granted if adequate control is demonstrated. The essential use concept could therefore not be used in this route for deciding on whether or not to grant an authorisation. Under both the socio-economic and adequate control routes for authorisation, the essential use concept could be considered when setting the review period of granted authorisations. Article 60(8) as this allows decisions for review periods to take into account socio-economic benefits and implications (as in Article 60(4)). **Sub-option B** The essential use concept would be introduced through an implementing regulation, therefore sub-option B would not require any legal changes to the enacting terms of REACH. The legal basis for introducing such an implementing act would be Article 291 of the TFEU and Article 132 of REACH. Article 291 of the TFEU states that where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission, or, in duly justified specific cases and in the cases provided for in Articles 24 and 26 of the Treaty on European Union, on the Council. Article 132 of REACH states that the measures necessary to put the provisions of this Regulation efficiently into effect shall be adopted in accordance with the procedure referred to in Article 133(3). Importantly, implementing acts cannot introduce new provisions, they can only reinforce the existing provisions. Therefore, sub-option B would be applied in the same way as sub-option A (with the same legal feasibility for introduction of the essential use concept in restriction and authorisation). In the end, it is the Commission's responsibility to conclude on the legal feasibility of sub-options (A and B) considered. **Sub-options C and D** would require legal changes to the enacting terms of REACH, which are legally feasible in the context of the revision of REACH.
Technical feasibility	The provision and assessment of technical and scientific information against the essential use criteria, while challenging, are not a constraint to the implementation of the concept, for all sub-options. The elaboration of well-defined criteria, as well as supporting guidance, should improve the technical feasibility of all sub-options.
Previous policy choices	None of the sub-options have been ruled out by previous policy choices or mandates by EU institutions. On the contrary, the CSS mandates the Commission "to define criteria for essential uses to ensure that the most harmful chemicals are only allowed

Screening criteria	Screening of sub-options
	if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health".
Coherence with other EU policy objectives	The proposed introduction of an essential use concept in REACH is generally non-overlapping with (and hence coherent with) other EU legislation as it aims to phase out the most harmful chemicals. Sub-options are coherent with the CSS, the Green Deal, and the wider Sustainable Development Goals.
Expected effectiveness and efficiency	Due to their binding nature, sub-options B, C and D are more likely to achieve the objectives set out in the previous sections. Nevertheless, sub-option A is not discarded on these grounds and further assessment of the impacts follows this chapter. Sub-option C might be less efficient given that it would reduce the clarity of rules for granting authorisations via the adequate control route for authorisation, and therefore decrease predictability, however, the sub-option is not discarded on these grounds. Sub-option D may be less efficient as costs to industry would be higher, however, expected benefits would also be higher therefore the overall difference in efficiency is uncertain.
Proportionality	Sub-options appear to be proportionate based on the level of concern raised by certain uses of the most harmful chemicals (note that a further assessment of their impacts follows this chapter): i.e., sub-option A (guidance) is likely to result in lower benefits than sub-options B, C and D (due to its non-binding/voluntary nature), which is proportionate to the lower costs it will involve (compared to other sub-options which require additional regulation, in the form of legal acts or changes to the enacting terms of REACH).
Political feasibility	The introduction of the essential use concept (regardless of sub-options) would be politically feasible as there is a mandate for introducing the essential use concept from the CSS (a strategy which was broadly welcomed by the European Parliament, the Council and many industries, NGOs, Member States, etc.).
Relevance	All sub-options are relevant as they allow phasing out some uses of the most harmful chemicals.
Identifiability	A summary of the differences between the sub-options in terms of the relevant REACH provisions is provided below.

Route to derogation or authorisation	Essential use concept applicability in sub-option			
	A	B	C	D
Authorisation – adequate control route	×	×	×	✓ (replaced)
Authorisation – SEA route	~	~	~	✓ (replaced)
Restriction 68(1) and 68(2) – authority-driven derogation of general applicability	~	~	✓	✓
Restriction 68(1) and 68(2) – industry-driven derogation of general applicability	~	~	✓	✓
Restriction 68(1) and 68(2) – Industry-driven authorisations of individual applicability	~	~	✓	✓

✓ = mandatory application of the essential use concept in full; ~ = optional application of the essential use concept alongside existing processes; × = the essential use

Screening criteria	Screening of sub-options
	concept would not be applied to decide on whether to grant authorisations or derogations. This comparison shows that sub-options A and B are not likely to differ materially in terms of the proposed measures, their significant impacts or their distribution, and thus only one of these sub-options should be retained as per the Better Regulation Toolbox (tool #16, page 118 on screening of options). We recommend discarding sub-option B as the weaker of the two because it would likely be more burdensome due to the processes required to introduce implementing acts.

10.5 Outline the sub-options in greater depth

In this section, the sub-options A, B, C and D are described in greater depth. Note that we recommend removing sub-option B based on the above viability screening (on the basis of the criterion of identifiability), however we have kept all sub-options in the section below for completeness. The sub-options below are described in general terms as applicable to the baseline (i.e., before the reform of authorisation and restriction): depending on the preferred option for authorisation and restriction, parts of the options below may not be applicable (e.g. if the authorisation title is removed). The specific application of each sub-option (for the essential use concept) within each option for the reform of authorisation and restriction can be seen in Table 10.1.

10.5.1 Sub-option A: Guidance for the introduction of the essential use concept in authorisation and restriction

Sub-option A would consider the essential use concept within the current legal framework of REACH, i.e., as an interpretative principle in guidance.

The adequate control route for deciding whether to grant an authorisation would remain the same as under the baseline. In both the adequate control route and socio-economic route for authorisation, the essential use concept could be applied to decide on the duration of the time-limited review period of the authorisation, e.g. setting shorter periods for non-essential uses and longer periods for essential uses. In the socio-economic route for authorisation, the minimum conditions for granting an authorisation via this route would be the same as the baseline, i.e., the socio-economic benefits of the use-applied-for must outweigh the risks and there must be no suitable alternatives. Provided a use meets these conditions, the Commission could take into account any evidence of essentiality or non-essentiality for society to aid decision-making on whether to grant the authorisation or to determine the length of the review period. For example, in cases where essentiality or non-essentiality for society is easier to determine, this could be particularly useful.

Under the restriction title of REACH, the guidance could be used to prompt consideration of essentiality when deciding on the scope for a restriction (based on Commission discretion) and for applicants for derogations to provide evidence of essentiality for society (under policy options where industry-driven derogations are introduced).

It is likely that this sub-option would have procedural challenges as ECHA's committees may not be able to make recommendations on the basis of this information, however, the committees' opinions could be taken into account by the Commission when deciding to grant the authorisation or not.

Table 10.4 Sub-option A

Overview of sub-option A	Description
Instrument	REACH-specific guidance document (complementary to the horizontal guidance on the essential use concept), to guide the practical application of the essential use concept in authorisation and restriction (both under articles 68(1) and 68(2)).
Legal basis	Legal feasibility of the sub-options is detailed in Table 10.3. REACH-specific guidance documents are provided to assist stakeholders in implementing legislation. They are **not legally binding**. The objective of these documents is to facilitate the implementation of REACH by describing good practice on how to fulfil the obligations. There are already quite a number of guidance documents available on REACH: for example, the guidance on registration, on socio-economic analysis for authorisation, etc. Note, however, that the Commission could, in principle, decide to systematically resort to the essential use concept for applications for authorisation and derogation from restriction.
Key mechanisms and activities	• A guidance document, developed by the Commission and ECHA with the participation of industry, Member States, NGOs would introduce the essential use concept in the authorisation and restriction provisions and processes. This would likely require the update of two existing guidance documents prepared by ECHA on the socio-economic analysis for authorisation and restrictions and on the analysis of alternatives. The REACH-specific guidance document(s) would complement the guidance document on the horizontal essential use concept (see part B of this report). • Within socio-economic route for authorisation, information on essentiality could be provided as part of SEA and be used to inform the opinions of the ECHA committees and the decisions of the Commission. • In both the SEA and the adequate control routes for authorisation, the essential use concept could be part of the considerations for setting the review period (for example, setting shorter review period for non-essential uses). • For the restriction process, the essential use concept could be implemented to scope the restriction (e.g. defining uses not covered by the restriction proposal). • RAC/SEAC would continue to provide scientific opinions (covering scientific and technical elements of the assessment in the field of authorisations and restrictions, but not on the more political aspect of whether a use is essential for society). It should be considered whether another (new or existing) committee would need to provide an opinion on whether the use is critical for the functioning of society or necessary for health and/or safety, e.g. the REACH Committee, the Member State Committee (MSC) or another ECHA Committee. • The Commission would take these scientific opinions into account in preparing proposals for deciding whether to grant authorisations or restricting substances and take a final decision on whether the legal conditions are met for granting an authorisation or an exemption to restriction.
Inputs	• Human and financial resources from ECHA and the Commission to develop the guidance document and assess the evidence for authorisation or exemptions to restrictions. • Human and financial resources from industry to provide evidence against the essential use criteria.
Outputs	• Derogations from restrictions granted on the basis of socio-economic considerations and analysis of alternatives, with optional consideration for

Overview of sub-option A	Description
	essentiality for society. Authorisations granted via the socio-economic route with optional consideration for essentiality or granted via the adequate control route with optional consideration for essentiality for society in determining the time-limited review period. Time-limited review periods for authorisations could be informed by essentiality for society. The adequate control route for authorisation would remain.

10.5.2 Sub-option B: Implementing regulation for the introduction of the essential use concept in authorisation and restriction

Sub-option B would consider the essential use concept within the current legal framework of REACH, e.g. as an interpretative principle in implementing legislation. This sub-option would result in the same changes to authorisation and restriction as sub-option A, with the only difference being the mechanism of introduction of the concept into REACH, which would mean that sub-option A would be non-binding, while sub-option B would be legally binding. Despite this difference, application of the essential use concept would be optional in both sub-options.

Table 10.5 Sub-option B

Overview of sub-option B	Description
Instrument	Implementing regulation to introduce the implementation of the essential use concept in authorisation and restriction.
Legal basis	Legal feasibility of the sub-options is detailed in Table 10.3. An implementing regulation is directly applicable in all Member States of the EU. It is **legally binding**. Its aim is to ensure uniform implementation of European legislation.
Key mechanisms and activities	• An implementing regulation, initiated by the Commission and approved by a committee of representatives of the Member States (the REACH Committee), would introduce and implement the essential use concept in the REACH provisions of the authorisation and restriction processes. This could be accompanied by a REACH-specific guidance document on the practical introduction, e.g. updating of two existing guidance documents prepared by ECHA on the socio-economic analysis for authorisation and restrictions, and guidance on the analysis of alternatives that would complement a horizontal guidance document covering the essential use concept (as suggested in Part B of this report). • Within the socio-economic route for authorisation, the essential use concept would apply in the same way as sub-option A (as a complementary consideration to the existing criteria for granting an authorisation). • In both routes for authorisation, the essential use concept could be part of the considerations during the review period setting, for example, setting shorter review period for non-essential uses, as in sub-option A. • For the restriction process, the essential use concept could be implemented to scope the restriction (e.g. defining uses not covered by the restriction proposal). • RAC/SEAC would continue to provide scientific opinions (covering scientific and technical elements of the assessment in the field of authorisations and restrictions, but not on the more political aspect of whether a use is essential for society). It should be considered whether another (new or existing) committee would need to provide an opinion on whether the use is critical for

Overview of sub-option B	Description
	the functioning of society or necessary for health/safety, e.g. the REACH Committee, the Member State Committee (MSC) or another ECHA Committee. • The Commission would take these scientific opinions into account and may grant an authorisation or an exemption to restriction based on whether the legal conditions are met but will also take other aspects into account, including the essential use concept as introduced.
Inputs	• Human and financial resources from ECHA and the Commission to develop the implementing regulation and assess the evidence for authorisation or exemptions to restrictions. • Human and financial resources from industry to provide evidence against the essential use criteria.
Outputs	• Derogations from restrictions granted on the basis of socio-economic considerations and analysis of alternatives, with optional consideration for essentiality for society. Authorisations granted via the socio-economic route with optional consideration for essentiality for society (within SEA) or granted via the adequate control route with optional consideration for essentiality in determining the time-limited review period. Time-limited review periods for authorisations could be informed by essentiality for society. The adequate control route for authorisation would remain.

10.5.3 Sub-option C: Introduction of legal changes in REACH for essential use under authorisation and restriction, as a complement to SEA route (adequate control route remains applicable)

Sub-option C would include the essential use concept via legal changes to the enacting terms of REACH under the authorisation and restriction titles.

In sub-option C, the adequate control route would remain applicable, with possible modifications. It is important to note that changes to the adequate control route are beyond the scope of this project, and therefore, it will be important to consider in the future how this sub-option fits with other potential changes.

Similar to sub-options A and B, the essential use concept could be applied to decide on the duration of the time-limited review period of authorisations and could apply within the socio-economic route for authorisation.

In restriction, the essential use concept would be applied to help authorities set the scope for restrictions (as in sub-options A and B). In policy options where requests for derogations (with applicant-specific or general applicability) can be formally made by companies, this sub-option would require the essential use concept to be used to assess applications.

Table 10.6 Sub-option C

Overview of sub-option C	Description
Instrument	Legal changes to the enacting terms of REACH (titles on authorisation and restriction) to introduce the implementation of the essential use concept in authorisation and restriction.
Legal basis	Legal feasibility of the sub-options is detailed in Table 10.3. By being incorporated within the titles on authorisation and restriction, the essential use concept would be directly applicable in all Member States of the EU. This is **legally binding**. This would therefore apply to decisions that are taken after revisions to REACH apply.
Key mechanisms and activities	• Legal changes, through the targeted revision of REACH initiated by the Commission and approved by co-decision (i.e., European Parliament and Council), would introduce the implementation of the essential use concept in the authorisation and restriction provisions under their respective titles. • This could be accompanied by a REACH-specific guidance document on the practical introduction, e.g. by updating of two existing guidance documents prepared by ECHA on the socio-economic analysis for authorisation and restrictions and guidance on the analysis of alternatives that would complement a horizontal guidance document covering the essential use concept (as suggested in Part B of this report). • The essential use concept would be used in the same way as in sub-options A and B for authorisation. • In restrictions, the essential use concept would be a mandatory tool for assessing whether to introduce derogations (authority-driven and industry driven derogations). • RAC/SEAC would continue to provide scientific opinions (covering scientific and technical elements of the assessment in the field of authorisations and restrictions, but not on the more political aspect of whether a use is essential for society). • It should be considered whether another (new or existing) committee would need to provide an opinion on whether the use is critical for the functioning of society and/or necessary for health/ safety, e.g. the REACH Committee, the Member State Committee (MSC) or another ECHA Committee. • The Commission would take these opinions into account and make a final decision on whether the legal conditions are met for granting an authorisation (under both routes of authorisation) or derogations to restriction based on Article 68(1) and 68(2).
Inputs	• Human and financial resources from the Commission to develop the legal changes to the enacting terms of REACH. • Resources from ECHA and the Commission to assess the evidence for authorisation or exemptions to restrictions and develop the guidance document to support the implementation of the legislative change. • Human and financial resources from industry to provide evidence against the essential use criteria.
Outputs	• Authorisations and derogations from restrictions granted on the basis of a hybrid approach of socio-economic/adequate control routes and the essential use concept. • Derogations to restrictions under Article 68(1) and 68 (2) granted on the basis of the essential use concept.

10.5.4 Sub-option D: Introduction of legal changes in REACH for essential use under authorisation and restriction, as a replacement to SEA route (adequate control route is removed)

Sub-option D would include the essential use concept via legal changes to the enacting terms of REACH under the authorisation and restriction titles. In sub-option D, the essential use concept would replace current criteria for deciding on authorisations or derogations from restrictions in accordance with Article 68(1). SEA would remain part of the restriction dossiers under Article 68(1); the essential use concept would only apply to derogations from restrictions. Derogations from Article 68(2) restrictions could be granted based only on the essential use concept.

The adequate control route in authorisation would be removed and fully replaced by the essential use concept under sub-option D. This sub-option would imply that all uses are authorised following only the essential use concept.

Table 10.7 Sub-option D

Overview of sub-option D	Description
Instrument	Legal changes to the enacting terms of REACH (titles on authorisation and restriction) to introduce the implementation of the essential use concept in authorisation and restriction.
Legal basis	Legal feasibility of the sub-options is detailed in Table 10.3. By being incorporated within the titles on authorisation and restriction, the essential use concept would be directly applicable in all Member States of the EU. This is **legally binding**. This would therefore apply to decisions that are taken after revisions to REACH apply.
Key mechanisms and activities	• Legal changes, through the targeted revision of REACH initiated by the Commission and approved by co-decision (i.e., European Parliament and Council) would introduce the implementation of the essential use concept in the authorisation and restriction provisions under their respective titles. • This could be accompanied by a REACH-specific guidance document on the practical introduction, e.g. updating of two existing guidance documents prepared by ECHA on the socio-economic analysis for authorisation and restrictions and guidance on the analysis of alternatives that would complement a horizontal guidance document covering the essential use concept (as suggested in Part B of this report). • The essential use concept would replace the adequate control route criteria, together with the risk-benefit comparison (demonstrated usually through socio-economic analysis) and the lack of alternatives criterion in the socio-economic route for authorisation and would replace the socio-economic analysis in derogations to restrictions. Accordingly, the essential use concept would be the only tool to assess and justify authorisations. • In restrictions, the essential use concept would be a mandatory tool for assessing whether to introduce derogations (authority-driven and industry driven derogations), under both Article 68(1) and Article 68(2). • RAC/SEAC would continue to provide scientific opinions (covering scientific and technical elements of the assessment in the field of authorisations and restrictions, but not on the more political aspect of whether a use is essential for society). • It should be considered whether another (new or existing) committee would need to provide an opinion on whether the use is critical for the functioning of society and/or necessary for health/safety, e.g. the REACH Committee, the Member State Committee (MSC) or another ECHA Committee.

Overview of sub-option D	Description
	• The Commission would take these opinions into account and make a final decision on whether the legal conditions are met for granting an authorisation or derogations to restriction based on Article 68(1) and 68(2).
Inputs	• Human and financial resources from the Commission to develop the legal changes to the enacting terms of REACH. • Resources from ECHA and the Commission to assess the evidence for authorisation or exemptions from restrictions and develop the guidance document to support the implementation of the legislative change. • Human and financial resources from industry to provide evidence against the essential use criteria.
Outputs	• Authorisations and derogations to restrictions granted on the basis of the essential use concept only.

10.5.5 Common features for all options

This section provides further information on common features for all sub-options, in terms of:

- Information to be provided to prove that a use is essential for society;
- Burden of proof; and
- Assessment of evidence and final decision.

Information to be provided to prove that a use is essential for society

As discussed in the previous section on criteria for the essential use concept (Part B of this report), the **application** of the criteria of necessity for health/safety, of criticality for the functioning of society and of non-availability of alternatives are likely to evolve through time as societal needs may evolve through time. Therefore, the type of information to be provided to prove fulfilment of each of those criteria may change as well. Nevertheless, Table 10.8 provides an indication of possible information needs to demonstrate under REACH that a use is necessary for health/safety, critical for the functioning of society and for the lack of alternatives, based on feedback from the targeted survey, interviews and the workshop.

Table 10.8 Information to be provided

Criteria and information needs	Information requirements

General information on use and substance	• Information on the use of the substance considered for the assessment, i.e., description of the use, relevant product or process relevant sectors affected, etc.
	• Key elements for describing a use: i.e.,
	  ○ use name;
	  ○ further description of use, life cycle stage, sectors of use (identification of the markets and particular settings in which the substances is used);
	  ○ description of the different activities contributing to the use (from human health and environment perspective, e.g. product category,

Criteria and information needs	Information requirements
	process category, article category or environmental release category based on the ECHA guidance on use description[152]); and ○ technical function of the substance in the use. • Note that such a description may need to be sufficiently precise to allow for the assessment of availability of alternatives and necessity for health, safety or criticality for the functioning of society. ECHA has developed guidance on those key elements for describing a use[153] for the purpose of authorisation applications. The way uses have been described in applications for authorisation has caused a lot of concerns and challenges in decision-making, however, the guidance has been updated following the first case law and could therefore be considered as a basis which may need further adjustments when developing the information needs under the essential use concept.
Criterion on necessity for health and safety	• A case-by-case approach to gathering and selecting the relevant information may be needed to assess the necessity for health/safety, for example, based on the level of analysis and scrutiny required to prove the fulfilment of the criterion for a given use. For example, some uses may be directly linked to severe health issues and therefore require less information to be gathered. However, some uses may have indirect links to health and safety and therefore require more information and scrutiny. • Information provided should include: ○ Evidence (scientific and technical data and justification) that the use of the substance (in the considered application) is necessary for health and/or safety. Horizontal guidance to define the criterion (e.g. as proposed in Part B of this report) could provide examples of which uses may be deemed necessary for health and safety and what evidence is needed. This could include details of what health/safety function is provided by or is necessary within the end product/service, and how the use of the substance contributes to achieving that. This will likely be substance- and use-specific. The information should be sufficient to show that the health/safety function cannot be achieved without the use of the substance, i.e., the product or process could not function without the substance. This may be a qualitative explanation supported by reputable sources or at least validation by third parties. Guidance on the quality and robustness of information provided could be further developed by the Commission and/or ECHA, as relevant. Existing guidance (e.g. on the format for analysis of alternatives and SEA) could be a starting point to indicate that all assumptions should be documented, relevant sources of information (supply chain consultations, data searches, information on R&D, etc.) are cited; certainty and confidence in the explanation and valuation should be discussed, etc. ○ To strengthen the argument that a use is necessary for health/safety, information on the anticipated impacts on health/safety if the substance was not used should be provided. This should focus on societal impacts, for example, impacts on health metrics such as disability-adjusted life years, life expectancy for the general population/vulnerable groups/patients with certain illnesses etc., disease incidence, premature mortality, quality-adjusted life-years. Qualitative information on the severity of health impacts may be

[152] European Chemicals Agency ECHA, (2015). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description. ECHA-15-G-11-EN. December 2015.
[153] European Chemicals Agency, ECHA (2017). How to develop use descriptions in applications for authorisation. ECHA-17-H-07-EN. June 2017.

Criteria and information needs	Information requirements
	included (based on reputable sources). Information on necessity for safety may include predicted number of accidents if the substance was not used. This consideration of anticipated impacts does not cover economic impacts to individual companies or sectors and would focuses only on societal impacts.
Criterion for criticality for the functioning of society	• A case-by-case approach to gathering and selecting the relevant information may be needed to assess the criticality for the functioning of society, for example, based on the level of analysis and scrutiny required to prove the fulfilment of the criterion for a given use. Some uses may be more clearly linked to the functioning of society and therefore require less information to be gathered, however, some uses may have indirect links and therefore require more information and scrutiny. • Information provided should include: ○ Evidence (scientific and technical data and justification) that the use of the substance (in the considered applications) is critical for the functioning of the society. Horizontal guidance to define the criterion (as proposed in Part B of this report) could provide examples of which uses may be deemed critical for society and what evidence is needed. This could include details of what critical function is provided by or is necessary within the end product/service, and how the use of the substance contributes to achieving that. This will likely be substance- and use-specific. The information should be sufficient to show that the service to society provided by the use cannot be achieved without the use of the substance, i.e., if the product or process could not function without the substance and if there are no other ways to deliver the service to society. This may be a qualitative explanation supported by reputable sources or at least validation by third parties. Guidance on the quality and robustness of information provided could be further developed by the Commission and/or ECHA, as relevant. Existing guidance (e.g. on the format for analysis of alternatives and SEA) could be a starting point to indicate that all assumptions should be documented, relevant sources of information (supply chain consultations, data searches, information on R&D, etc.) are cited; certainty and confidence in the explanation and valuation should be discussed, etc. ○ To strengthen the argument that a use is critical for the functioning of society, information on the anticipated impacts/effects on functioning of society if the substance was not used should be provided. This should focus on societal impacts, for example, if a use is critical to avoid natural disasters or other crises (pandemics, terror attacks etc.) the severity of impacts of these crises should be described, e.g. in terms of public safety and security or lost infrastructure / public goods required for society to function. This consideration of anticipated impacts/effects does not cover economic impacts such as costs to companies, although some impacts on society may be monetised.
Criterion on lack of alternatives	• Information provided should include: ○ Description of the substance function, role of the substance in the use and, if appropriate, information on the level of performance for the substance (within required operational conditions) in the use, as well as if any standards are mandatory related to performance and safety levels. With regard to loss of performance, industry should consider that there may be some loss of performance that can be tolerated in order to reduce impacts from the most harmful chemicals, for example, loss of performance should be accepted so

Criteria and information needs	Information requirements
	long as it does not compromise the use, i.e., so that the use still delivers the service which makes it critical for the functioning of society or necessary for health/safety. This should be based on consultation and research (e.g. customer surveys, market analysis or referring to relevant mandatory requirements or technical standards); and in case where this loss is unacceptable, it should be justified why from a societal point of view. ○ Identification of possible alternative substances, materials and technologies: list of possible alternatives and description of efforts made to identify those. Respondents to the consultation noted that alternatives should be viewed in a broad sense and should include alternative technologies, practices, processes etc., as is currently the case under REACH authorisation. ○ Suitability and availability of possible alternatives. This includes information on the technical and economic feasibility, the reduction in overall risk due to the transition to the alternative, the availability of alternatives (overall, not only from the applicant's perspective). ECHA has already developed guidance for the analysis of alternatives under authorisation and restriction. Note that, according to the horizontal essential use criteria, the suitability should be assessed not only from the applicant's perspective but also taking into account the suitability of alternatives in general across the EU. ○ The results of a comparative assessment related to risks to the environment and health between the substance in the use and the alternatives. This assessment should include considerations on overall risks of the substance and its alternative across life cycles. For example, the guidance for application for authorisation[154] states that "ideally the assessment should address all possible risks throughout the entire lifecycle of the substances including all relevant compartments and populations, even those not originally associated with the identified risks". ○ The underlying methodology for the assessment of alternatives should be provided.
Minimisation of the essential use, as well as exposure, emissions, and risks	• Information provided should include: ○ Evidence that the industry is taking all steps to minimise the essential use and any associated emissions of and exposure to the controlled substance at all lifecycle stages, including waste and recycling. A range of risk management measures in individual exposure scenarios may need be included for each use, for example, enhanced containment, ventilation, emissions abatement equipment, safe waste handling. ▪ The evidence must be sufficient to demonstrate that exposure to humans and emissions to the environment are minimised as far as possible. ▪ Information on current risk management measures and operational conditions (per individual exposure scenarios) should be included to demonstrate the measures taken by the applicant to minimise exposure and emissions. ▪ Monitoring should be conducted to prove and ensure that exposure/emissions are sufficiently minimised over the full time period of the derogation/authorisation.

[154] European Chemicals Agency, ECHA, (2021). Guidance on the preparation of an application for authorisation. ECHA-20-G-03-EN. January 2021.

Criteria and information needs	Information requirements

Appropriate effort to substitute the essential use	• Evidence demonstrating that an appropriate effort is being made to develop, evaluate, commercialise, and secure regulatory approval of alternatives.
	• A substitution plan should be included in any application for derogation/authorisation, including:
	  ○ the factors affecting the transfer to the substitute(s);
	  ○ the actions required for transferring to the substitute;
	  ○ the time needed for each of those actions;
	  ○ consultation with the supply chain on actions and timings;
	  ○ management plan for the actions including consideration of uncertainties and mitigation; and
	  ○ plan to follow up the progress of the substitution.
	• In particular, where alternatives exist but are not yet feasible, this should justify the amount of time required for actions. Where alternatives do not yet exist, the plan for R&D should be detailed.
	• During the derogation/authorisation, industry should continue to demonstrate effort to substitute. This is similar to current requirements for progress-limited derogations under REACH, which are contingent upon industry demonstrating progress in R&D. Monitoring schemes, reporting requirements, and schedules can help.

Burden of proof

This section further details who should bear the burden of proof in demonstrating that the use of one the most harmful chemicals is essential for society. For all criteria, the burden of proof will ultimately have to fall on the (group of) stakeholder(s) with an interest in the use, as only these stakeholders will have the insights needed to demonstrate criticality for the functioning of society, necessity for health/safety, and the absence of alternatives. There was general feedback from the consultation activities that, despite the burden of proof falling on one specific stakeholder, all actors with available and reliable data should have the possibility to provide input to those assessments.

Table 10.9 Burden of proof

Criteria	Burden of proof
Criterion on necessity for health and safety	**Stakeholder views:** • Close to 60% of respondents to the survey agree, across all stakeholder types, that industry should bear the burden of proof. It was recommended that the manufacturers of the substance primarily bear the burden of proof, but systems (e.g. consultations) should be established so that the whole supply chain can be involved in the provision of information: for example, downstream users / end users were consistently reported as having the information on substance use and function required for the assessment. Other parts of industries to be involved mentioned in the survey include importers/distributers of chemicals, as well as actors responsible for the design specifications of a product. • Only 2% and 3% of respondents (all companies) thought ECHA and Member States Competent Authorities respectively should bear the burden of proof. It was noted that in some cases, Member States Competent Authorities may have specific reasons to demonstrate the need for retaining a certain use, in which case, they could provide justification as well. • Over 35% of survey respondents selected 'other' (than industry, ECHA or MSCA) should bear the burden of proof for this criterion. Most of those respondents provided consistent suggestions that, while the burden should primarily fall on industry, it should be possible for ECHA, MSCAs and other EU bodies to provide inputs in order to validate the information provided by industry, and there should be collaboration between company representatives or consortia and ECHA. There were some responses to establish a new body or committee but this view was not widely shared. **Conclusion:** • **Industry (manufacturers, suppliers, and downstream users) should bear the burden of proof in demonstrating that the use of one of the most harmful chemicals is necessary for health/safety, with support from actors along the supply chain, e.g. manufacturers of complex products containing articles containing the chemical.**
Criterion for criticality for the functioning of society	**Stakeholder views:** • As for the previous criterion, close to 60% of respondents to the survey agree, across all stakeholder types, that industry should bear the burden of proof. It was recommended that the manufacturers of the substance primarily bear the burden of proof, but systems should be established so that the whole supply chain can be involved in the provision of information, e.g. downstream users / end users. • Only 2% and 4% of respondents (all companies) thought ECHA and Member States Competent Authorities (respectively) should bear the burden of proof. • Over 35% of survey respondents selected 'other' (than industry, ECHA or MSCA) should bear the burden of proof for this criterion. Similarly, these respondents suggested that the burden of proof should fall on a combination of actors, including industry, MSCA and ECHA, with the primary burden on industry but not excluding any other parties. **Conclusion:** • **Industry (manufacturers, suppliers, and downstream users) should bear the burden of proof in demonstrating that the use of one of the most harmful chemicals is critical for the functioning of the society, with support from actors along the supply chain, e.g. manufacturers of complex products containing articles containing the chemical.**

Criteria	Burden of proof
Criterion on lack of alternatives	**Stakeholder views:** • Close to 65% of survey respondents agree, across all stakeholder types, that industry should bear the burden of proof as industry is believed to have the best knowledge on the substance and its function, which may not be publicly available. However, it is worth noting that knowledge of alternatives may come from elsewhere, e.g. end-users of products, in particular, for alternative materials, technologies, products, and processes rather than chemical alternatives. • Only 3% and 5% of respondents (all companies and business associations) thought ECHA and Member States Competent Authorities respectively should bear the burden of proof. There was a suggestion that the process could be facilitated and coordinated by ECHA. • Over 25% of survey respondents selected 'other' (than industry, ECHA or MSCA) should bear the burden of proof for this criterion. Similarly, there was consistent feedback that collaboration between industry, MSCAs and ECHA was critical. A suggestion, not widely supported though, was to establish a new independent body to assess the availability of alternatives. Finally, it was raised that inputs from academia will be key to demonstrate this criterion. **Conclusion:** • **Actors along the supply chain should bear the burden of proof in demonstrating that there are no alternatives that are acceptable from the standpoint of environment and health**. **Other stakeholders (including academia for example) should be invited to provide evidence on alternatives, e.g. through consultation.**

Assessment of evidence against criteria

Competent bodies making the assessments and decisions based on the essential use criteria must be accountable for what those decisions conclude about essentiality of uses for society. For political legitimacy, to assess against the criteria beyond the technical aspects, these actors should be supported with clear and thorough guidance on the underpinning principles of the essential use concept and criteria. Subjectivity should be avoided as far as possible, however, due to the inherently political nature of defining a use as essential for society, inevitably it will be necessary to apply some elements of subjective judgement, rather than have defined criteria that capture all possible situations (in line with the proposed criteria and elements in section 3 of this report).

While the table below captures feedback on the **responsibilities for the assessment** of the uses as to whether they meet the criteria, a re-occurring perspective, highlighted in the literature and through the stakeholder survey, is that **affected stakeholders should be consulted in this assessment of essentiality of the considered uses**. For example, through public consultations, working groups or other participatory methods including society. The involvement of society / EU citizens in the assessment was proposed by several stakeholders, particularly for some specific aspects of the concept. Involvement of EU citizens may be a way to determine essentiality when considering more controversial issues such as cultural heritage aspects.

Table 10.10 Assessment of evidence and final decision

Criteria	Responsible body to assess this criterion
Criterion on necessity for health and safety	**Stakeholder views:** • According to the targeted survey, the preferred responsible authority to assess this criterion would be a new body or committee with 38% of responses. Only 13% of respondents selected one of the ECHA committees, and 8.5% the European Commission in consultation with the REACH committee. There was an even poorer support for the Member State Committee of ECHA and the ECHA Secretariat. • Around 35% of respondents selected another authority than those proposed in the survey. Some of the suggestions included: a combination of the actors mentioned in the multiple choice, at least the entities that were involved in the assessment so far (RAC, SEAC, MSC of ECHA) and the European Commission, elected officials accountable to the public. It was also noted that depending on the application considered, EASA, ESA, EMA, ministries of defence, etc. may need to be involved. Several respondents who had selected 'a new body or committee' further indicated that such a new body should gather existing groups such as SEAC, RAC, SCCS, but should be supplemented by, for example, technical experts and experts from the supply chain. • Overall, there were diverging views with some respondents noting that the existing committees in their current form would lack some of the expertise necessary to make the assessment, while others, in contrast, noted that the relevant institutions already exist to make the assessment. **Conclusion:** • **RAC and SEAC do not currently assess essentiality (or criteria thereof). In addition, this criterion includes political elements/considerations (see guidance elements to define the criterion proposed in part B of this report). Therefore, it is questionable whether ECHA and its current scientific committees which provide science-based opinions would be best positioned to carry out the assessment of this criterion. In this context, the Commission could explore ways for the Member State Committee or a new committee to assess the criterion of necessity for health/ safety.**
Criterion for criticality for the functioning of society	**Stakeholder views:** • Similarly to the previous criterion, according to the targeted survey, the preferred responsible authority to assess this criterion would be a new body or committee (ca. 35% of responses). Reasoning included the belief that existing committees do not currently have the necessary expertise to make these assessments. Only ca. 10% of respondents selected one of the ECHA committees, or the European Commission in consultation with the REACH committee. Those selecting the European Commission noted that this decision was mainly political (unlike the previous criterion). Even lower support was stated for the Member State Committee of ECHA and the ECHA Secretariat, as for the previous criterion. • Around 35% of respondents selected another authority than those proposed in the survey. Some of the suggestions included: a combination of the actors mentioned in the multiple choice, at least the entities that were involved in the assessment so far (RAC, SEAC, MSC of ECHA) and the European Commission, elected officials accountable to the public, the European Commission alone or with independent committee of experts or SCCS or competent authorities from Member States. • The feedback from respondents to the survey on this criterion emphasised on the need for both a political and scientific assessment of the evidence.

Criteria	Responsible body to assess this criterion
	Conclusion: • **Similarly to the previous criterion, RAC and SEAC do not currently assess essentiality (or criteria thereof). In addition, this criterion includes political elements/considerations (see guidance elements to define the criterion proposed in part B of this report). Therefore, it is questionable whether ECHA and its current scientific committees which provide science-based opinions would be best positioned to carry out the assessment of this criterion. In this context, the Commission could explore ways for the Member State Committee or a new committee to assess the criterion of criticality for the functioning of society.**
Criterion on lack of alternatives	**Stakeholder views:** • Unlike the two previous criteria, the preferred responsible authority (according to the respondents to the targeted survey) to assess this criterion would be one of the ECHA committees, with close to 30% of responses in favour. Respondents noted that RAC and SEAC indeed already had the necessary expertise. Over 20% of respondents selected a new body or committee for this criterion. • In addition to the ECHA committees, there were suggestions to involve EASA, ESA, ministries of defence, SCCS or a new scientific committee, industry and Member States Competent Authorities. • **Conclusion: Given the experience of SEAC in assessing the availability of alternatives and RAC in assessing the risks from alternatives, empowering these existing committees could be more effective and efficient than establishing new committees or involving other bodies.**
Final decision on essentiality for society	• **The authority responsible for a final decision on essentiality (based on the assessment of necessity for the functioning of society, criticality for health/safety, and alternatives) would be the same authority deciding on whether an authorisation or a derogation from a restriction should be granted, i.e., the European Commission.**

10.5.6 Additional parameters

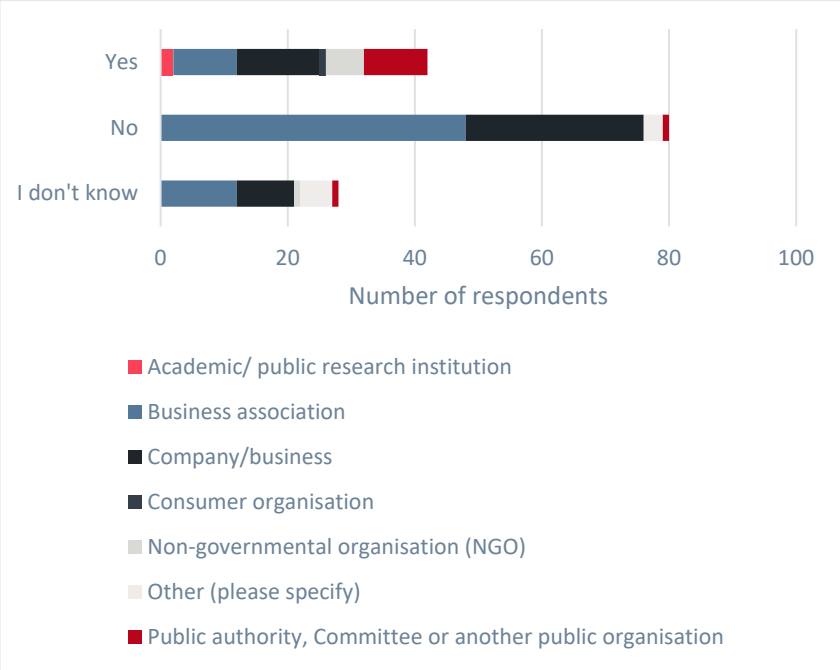
The table below sets out a number of alternative parameters that are being considered in order to define how the sub-options would be implemented in practice. Initial considerations for the screening of those sub-options are included in the table below, including feedback from the consultation.

For sub-options B, C and D (see previous section), additional parameters are proposed, which are combinations of the following procedural features, i.e., changes in the steps or sequences to be carried out, or provisions of minor importance.

Table 10.11 Overview of parameters

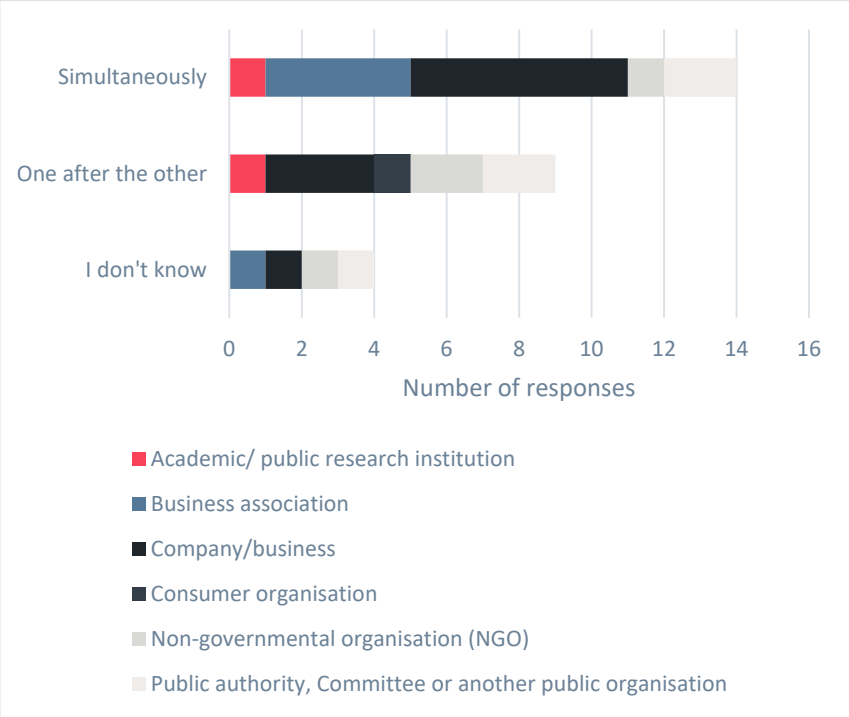
Parameter	Stakeholder views	Conclusions
1. Initial rapid screening for alternative products or services available on the market in the same category **A screening for alternative products or services available on the market in the same category could be a first step to quickly filter out non-essential uses, with a view to shorten the decision-making process. If such products without the use of the most harmful chemicals are available for the same product category, there would be no need to continue assessing the essentiality of the use further. When this is not easy to judge, an assessment of the necessity for health and safety and criticality for the functioning of society of the use claimed as essential for society would be the next step. The aim would be to avoid time-consuming assessments of criticality for the functioning of society/necessity for health/safety and that of alternatives for potentially non-essential uses. Key steps for this screening would have to be further detailed, including:** • **Rapid screening of product categories (by ECHA)**	• 61.6% of respondents did not believe an initial screening for alternative products available on the market would simplify and speed up decision-making. • 26.5% of respondents believed an initial screening for alternative products available on the market would simplify and speed up decision-making. • In general, academia and NGOs were more in favour of this screening step whereas business associations were more strongly against. • Those who disagreed argued that such a screening would result in an inadequate evaluation of alternatives, and that an in-depth analysis would be required on technical performance, combination of functionalities, lifecycle of application, sustainability, circularity and carbon footprint etc. to avoid regrettable substitutions. They argued that the function of an article without a particular substance might be substantially different following a rapid screening of alternatives, which is particularly the case for complex products. • However, those who agreed believed that the screening would lead to a simplification of the overall process and would reduce the effort and costs involved. Others argued that similar screenings are already standard practice. However, they argued that clear criteria should be developed to guide the assessment. • The feedback from the survey was consistent with the feedback received at the workshop, where several stakeholders warned (as noted above) that the complexity and time requirement of an assessment of alternatives was being underestimated in this rapid screening. Some expressed doubts that "screening" will be enough for an informed decision and a detailed analysis will have to follow, which potentially increases the complexity and does not necessarily make the process easier or faster. A key argument against the assessment of alternatives being considered first is that a fast screening of alternatives can be based on incomplete or inaccurate information, leading to alternatives that are not appropriate for the considered uses. • Question from the targeted survey: Do you agree with the following statements?: An initial screening for alternative products available on the market, but without the most harmful chemical would simplify and speed up decision-making.	Based on our analysis and consistent feedback from the targeted survey, the workshop and CARACAL meeting, rapid screening for alternative products or services on the market in the same category would raise the following problems: • Difficulties to scope the screening (e.g. scoping product categories adequately); • Likely lack of or inaccurate information in a rapid screening step; • Complexity and time required to complete a screening likely to be underestimated.

Parameter	Stakeholder views	Conclusions
• **Defining relevant product categories (by ECHA) (although this step might not be needed depending on the option, e.g. based on information on essential uses that would be submitted at earlier stages, e.g. at the candidate listing step (to be aligned with changes suggested under the authorisation/restriction study) or during the consultation for listing on Annex XIV, there may be a public consultation in which the interested parties can submit and complement information on this)** • **Consultation on relevant product categories (by ECHA and industry)**	 • Another view from the workshop (from a Member State authority) called for a flexible approach and the possibility to decide for each individual case whether the screening should be done first for criticality for the functioning of society/necessity for health/safety or for alternatives. • Finally, the option to add an initial screening step was presented at the 45th Meeting of Competent Authorities for REACH and CLP (CARACAL) on 6 July 2022: overall, the feedback from authorities participating in the meeting was consistent with the above views, suggesting a preference for no screening steps.	
2. Initial rapid screening of criticality for the functioning of	• 53.3% of respondents did not believe that an initial screening for necessity/criticality would simplify and speed up decision-making.	Based on our analysis and consistent feedback from the targeted survey, the workshop and

Parameter	Stakeholder views	Conclusions
society and necessity for health/safety **Sorting out 'easy' cases where clearly non-critical (for the functioning of society)/ unnecessary (for health/safety) uses would not require an assessment of alternatives and be deemed as not essential. Clearly necessary (for health/safety) /critical (for the functioning of society) uses would require an assessment of alternatives to conclude whether the use is essential for society. Cases that are not clear-cut would require a full assessment of criticality (for the functioning of society)/necessity (for health/safety) and the assessment of alternatives. Key steps for this screening would have to be further detailed.**	• 28.0% of respondents believes that an initial screening for necessity for health/safety / criticality for the functioning of society would simplify and speed up decision-making. • Question from the targeted survey: Do you agree with the following statements?: An initial screening for necessity/criticality would simplify and speed up decision-making.  • In general, academia and NGOs were more in favour of this screening step whereas business associations were more strongly against. • In general, there were fewer arguments directly related to the initial rapid screening of criticality for the functioning of society and necessity for health/safety from any viewpoint in the targeted consultation. However, for those who argued that an initial rapid screening of criticality for the functioning of society and necessity for health/safety would not simplify and	CARACAL meeting, rapid screening of criticality for the functioning of society and necessity for health/safety would raise problems similar to the above screening: • Difficulties to scope the screening; • Likely lack of or inaccurate information in a rapid screening step; • Complexity and time required to complete a screening likely to be underestimated.

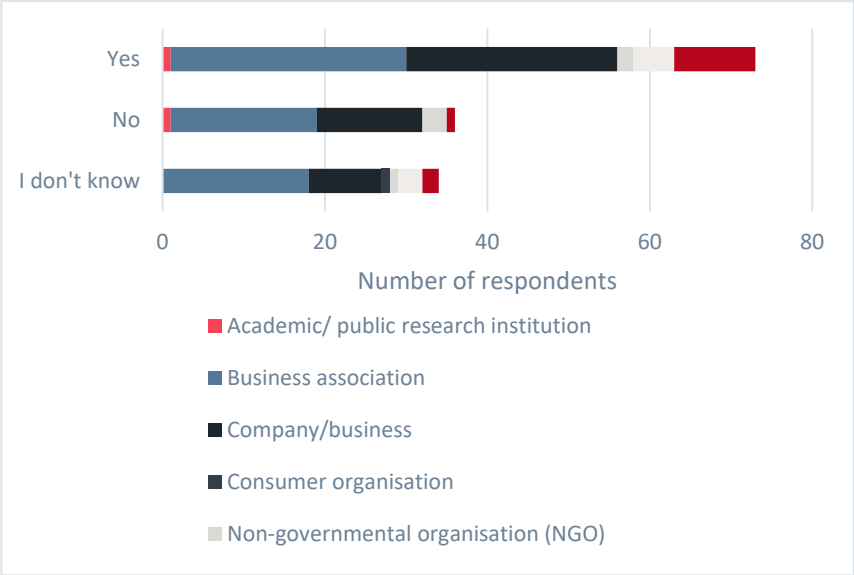
Parameter	Stakeholder views	Conclusions
	speed up decision-making, the reasons were usually that a more thorough assessment would be required. They argue that the complexity of products and their substances cannot be captured in a screening exercise. • Those who supported the concept of an initial rapid screening of criticality for the functioning of society and necessity for health/safety stated that the use of this screening could sometimes be beneficial and that it should come first in the overall process. • Finally, the option to add an initial screening step was presented at the 45th Meeting of Competent Authorities for REACH and CLP (CARACAL) on 6 July 2022: overall, the feedback from authorities participating in the meeting was consistent with the above views, suggesting a preference for no screening steps.	
3. Order of screening steps	• The targeted survey asked respondents what they thought the order in which the screening steps (parameters 1 and 2) are applied should be, if any. • Question: If you have selected 'both screenings', do you think the two screenings (on criticality/necessity and on alternatives) should be done simultaneously or should they be done one after the other?	Should such screenings apply, they could be run simultaneously, with flexibility at the Commission's discretion and depending on the information available, on a case-by-case basis.

Parameter	Stakeholder views	Conclusions



- 51.9% of respondents to this question indicated that the two screenings should be done simultaneously.
- 33.3% of respondents to this question indicated that the two screenings should be done one after the other.
- 3 of the respondents who thought that they should be done one after the other indicated that the analysis of alternatives should come first. This was to ensure that alternatives would not be available on the market.
- On the other hand, 6 of the respondents who thought that they should be done one after the other indicated that the screening for necessity for health/safety and criticality for the functioning of society should come first. This was because it was seen as the most efficient of the two approaches and because if necessity for health/safety and/or criticality for the

Parameter	Stakeholder views	Conclusions
	functioning of society is not shown, then the step of screening for an alternative becomes redundant. • Another argument made at the workshop was that the order of which screening should come first should be flexible and depend on the information available. In line with this, an EU agency participant proposed implementing a tier assessment that would look first at the criteria that are clearer and more easily accessible, then at those more time or energy demanding.	
4. Fall-back mechanisms for emergency and crisis situations **Applicable to sub-option C and D** **This would involve an additional fall-back mechanism in decision-making on essential uses for emergency situations.**	• 51.0% of respondents see a need for an additional fall-back mechanism for emergency situations for uses of the most harmful chemicals. • 25.2% of respondents do not see a need for an additional fall-back mechanism for emergency situations for uses of the most harmful chemicals. • Those who do see a need for this mechanism, expressed the need for a full, clear definition of 'emergency' but highlighted that such a mechanism would allow the timely and efficient response to unforeseen events. • Several respondents indicated the limitations of the Article 2(3) on REACH defence exemption. Others indicated that changes to the wording in this Article could encompass 'emergency situations'. • Question: Do you see a need for an additional fall-back mechanism for emergency situations for uses of the most harmful chemicals (until they are assessed as essential or not essential under REACH following a more in-depth assessment)?	Article 2(3) is limited in its scope to exemptions for cases in the interests of defence only. While the scope of Article 129 is wider, i.e., provisional measures can be taken if urgent action is essential to protect human health or the environment, its application is limited to changes requested by the Member States (as Article 2(3)). Such actions for emergency situation can thus not be taken by the European Commission. However, the Commission can act and revise Annex XVII or XIV at any time, according to Article 131, stating that "the Annexes may be amended in accordance with the procedure referred to in Article 133(4)", which should be used in cases of emergency situations that would not be covered under the two previous articles. This approach has been applied during the COVID-19 pandemic to modify the transitional arrangements in Annex XIV for uses of OPE in COVID-

Parameter	Stakeholder views	Conclusions
	 • At the workshop, a number of stakeholder groups agreed that there is a need for a fallback mechanism in case of an emergency (e.g. the case of COVID-19 pandemic was made as some substances were allowed for surfactants use e.g. under the BPR). A fallback mechanism could allow for the possibility for the use of one of the most harmful chemicals in emergency situations until the use is assessed as essential or not essential for society under REACH following a more in-depth assessment, or subsequently remove a derogation after it has been granted in case of an emergency. However, there was some disagreement regarding whether there needs to be additional mechanisms put in place under REACH. Stakeholders against a dedicated procedure for emergency situations argued it would be a distraction at this stage and is not necessary if everything works well, since it would otherwise add complexity to the assessment. Rather, they prioritised a need to focus on the functioning and efficiency of the essential use concept first. A representative from a Member State authority noted that there are regulatory processes in REACH that allow the Commission to take action if needed.	vaccines and COVID-diagnostic uses. Therefore, it is thought that an additional fall-back mechanism for emergency and crisis situations is not needed.

11 Impacts of the essential use concept for REACH

11.1 Overview

This section outlines:

- An explanation of how impacts have been compared to the baseline scenario in this chapter;
- A description of the assumptions and uncertainties which are key to underpinning the assessment; and,
- A description of the predicted environmental, social, and economic impacts.

Importantly, this chapter investigates the impacts of introducing the essential use concept in REACH to replace the approaches used under the baseline to justify whether authorisations should be granted and whether derogations to restrictions should be made. This chapter does not investigate, for example, the impact of allowing essential uses in isolation, rather, considers the net impacts of implementation of the concept. An explanation of how the impacts have been compared to the baseline is further explained in section 11.2.

Impacts are described broadly through sections 11.4 to 11.7 without differentiation between the policy options for the reform of authorisation and restriction and the sub-options for the essential use concept because the identified impacts are shared (to different extents) between all options. Differences in impacts between options are investigated in section 12. Furthermore, this project focuses specifically on the essential use concept and hence the impacts of the other measures associated with the reform of authorisation and restriction are beyond the scope of this project (as they are being investigated in parallel by VVA[155]).

It was not possible to conduct a quantitative assessment of impacts under this project. The predicted environmental, social, and economic impacts from the essential use concept are primarily dependent on: 1) the extent to which the essential use concept would change the proportion of uses of the most harmful chemicals which could be allowed; 2) the extent to which the essential use concept would change the complexity and efficiency of the restriction and authorisation processes. These factors are described qualitatively in this chapter, but ultimately, there is insufficient evidence to make an informed judgement on the quantitative changes expected from implementation of the essential use concept in REACH.

11.2 Comparison of impacts to the baseline scenario

All impacts are described relative to the baseline. The baseline reflects the current situation in terms of existing REACH processes. This is aligned with the baseline used under the VVA study on the reform of authorisation and restriction (VVA, Unpublished). Further information on the baseline is provided in section 10.2 of this report. To compare the essential use concept to the baseline, we have considered evidence from existing legislation and accompanying guidance documents as well as previous examples of derogations from restrictions and authorisations. The main comparison to the baseline, underpinning the description of all impacts, is the **change in *proportion* of derogated/authorised uses of the most harmful chemicals** expected from

[155] Valdani Vicari & Associati, VVA (Unpublished). 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, Third Draft Final Report [06/09/2022]

introduction of the essential use concept in comparison to the baseline (based on current derogations and authorisations). This change is expected because, under each policy option, the essential use concept would replace or complement the current rationale for restriction derogations and authorisations to some extent. Environmental, social, and economic impacts would all stem from this fundamental change.

Assessing the *relative change* in *proportion* of derogated/authorised uses allows this assessment to focus specifically on the impacts of the essential use concept, not the impacts of the other measures being considered under the reform of authorisation and restriction (which are being assessed under a separate study). This is important given that the other measures can also impact the number of uses of the most harmful chemicals (through changing the number of substances subject to restrictions or authorisation, in contrast to the essential use concept which would change the number of exemptions from those restrictions) and would influence the scope of substances which the essential use concept could apply to. Considering the absolute change in derogations and authorisations would therefore not only reflect impacts of the essential use concept, but also of the other measures.

For example, under policy options which increase the number of restrictions of substances (e.g. through extending GRA), the number of derogations needed would be higher. It would be misleading to infer that the greater number of derogations reflects an increase in the number of uses of the most harmful chemicals, because overall, the increased number of substances restricted would counter this impact. Focusing on the proportional change of derogations and authorisations ensures that only impacts of the essential use concept are assessed.

11.3 Assumptions and uncertainties

11.3.1 Assumptions

To predict environmental, social, and economic impacts, there must first be an understanding of the direct impacts that the essential use concept would cause, e.g. the number and identity of substances and uses which would be affected by the concept, in comparison to the number of substances and uses affected by current provisions in the REACH regulation. This is further scrutinised here to set out the assumptions which underpin this impact assessment.

The following assumptions are described below:

- Assumption 1 – The essential use concept would result in a reduced proportion of uses of the most harmful chemicals derogated from restriction in comparison to the baseline.
- Assumption 2 – The essential use concept would result in a reduced proportion of authorisations in comparison to the baseline.
- Assumption 3 – The essential use concept would encourage substitution of the most harmful chemicals to a greater degree than under the baseline.
- Assumption 4 – The essential use concept would increase the pressure to minimise the use, emissions, and exposure of uses which could be derogated or restricted, in comparison to the baseline.

Assumption 1 – The essential use concept would result in a reduced proportion of uses of the most harmful chemicals derogated from restriction in comparison to the baseline.

This assumption is based on a comparison between the essential use criteria and the current provisions for restriction in terms of stringency, i.e., the breadth of use types which could be derogated. In each policy option, the degree to which the essential use concept would replace elements of authorisation and restriction varies. This is explored in the section 10 on policy options

and in section 12, but the assumption is relevant for all sub-options, and therefore described here broadly by comparing the rationale for derogations under the essential use concept to the rationale for derogations under the baseline.

The following differences between the types of uses which could be justified for derogation using the essential use criteria and those which could be justified for derogation using current procedures for restrictions under **Article 68(1)** are recognised, based on ECHA guidance for the preparation of restriction dossiers[156]:

- Under the baseline, derogations could be allowed for uses where substitution would result in **significant socio-economic impacts or distortion to the internal market**. The essential use concept would not justify derogation for these uses (based on criteria under section B of this report).
- Under the baseline, derogations could be allowed based on the information and analysis presented in **socio-economic analysis (SEA)**. This includes information and analysis which could justify an essential use (e.g. high benefits to society in terms of health / safety / functioning of society) but is broader because it also includes purely economic considerations (costs to manufacturers, importers, downstream users and distributors). The essential use concept would only allow uses essential for society. There is a possibility that some uses could be justified for derogation by the essential use concept and not by SEA considerations, however, this is considered unlikely given that essential uses are those with significant societal importance, therefore SEA would likely show high benefits.

As such, the number of uses which could be justified for derogation based on the essential use concept is considered a small subset of uses which could be justified for derogation based on SEA considerations. This cannot be quantitatively assessed based on data available to the project team.

Some stakeholders raised concerns that the criteria could make it too easy for industry to claim that a use is essential for society and all uses related to the criteria could be derogated (e.g. any use related to health), which could result in an increase in number of uses allowed.

However, although the essential use criteria would guide the types of uses which could be deemed essential for society, it is a misunderstanding to think that there would be automatic derogations for any use related to health/safety/criticality for the functioning of society. For each use, the function provided by the substance in the product/process must be critically assessed to determine whether the use of the specific chemical is truly essential for society. The term “essential” indicates that derogations should be exceptional, only for cases where society has a significant need for the use. This was exemplified under the Montreal Protocol, where the essential use concept was effective in helping to phase out CFCs because it was clear that most uses were not “essential”. If applied under REACH, the Commission and other EU institutions would be required to make the final decision on which uses should be derogated or authorised (as is done under the baseline). Evaluation of whether the use meets the essential use criteria would be conducted to aid decision-making, but ultimately the Commission would need to make a political decision on whether the use is truly essential for society. Provided that this political decision interprets “essential” as meaning that derogations should be exceptional, this would alleviate risks that industry could too easily be granted derogations. These risks would be further mitigated by clarity of the horizontal (and legislation-specific) guidance documents which would minimise the potential breadth for “essential uses”, as well as the conclusions in section 10.5.5 to ensure the information provided to prove criticality for the functioning of society and/or the necessity for health, safety are supported by reputable sources or at least validation by third parties, and for the use of consultations in the assessment of whether acceptable alternatives are available.

[156] European Chemicals Agency, ECHA (2007). Guidance for the preparation of an Annex XV dossier for restrictions. (EC) No 1907/2006. December 2006.

Experience from past derogations shows that uses which could be derogated based on the essential use concept could likely also be derogated under the baseline, therefore, it is unlikely that the concept could result in more derogations. For example, perfluorooctanoic acid (PFOA) and perfluoroalkyl carboxylic acids (PFCAs) were derogated from restriction in protective clothing for workers, in uses which would likely qualify as necessary for health/safety (notably, these restrictions have been / are being taken over by the POPs Regulation, following addition of the substances to the Stockholm Convention). Derogations related to the criticality for the functioning of society (considering cultural and heritage aspects) also exist, for example, REACH Annex XVII entries 16 and 17 include derogations for the restoration and maintenance of works of art and historic buildings (relating to the criticality for society linked to cultural heritage listed in Part B).

There are also indications that the essential use concept might result in fewer and more narrower derogations because some derogations in the baseline have been broad in scope. For example, the derogation of cadmium for "safety reasons" (Annex XVII Entry 23, added immediately after the establishment of REACH in 2006) was criticised by Member States for being too broad, as "safety reasons" were not clearly defined. ECHA (2012) noted that the derogation was difficult to enforce given that a company could easily claim that any cadmium in articles is used for safety reasons. In 2015, ECHA specified that uses for "safety reasons" should be necessary to prevent accidents, for safety equipment, or show similar kinds of safety aspects. If the essential use concept had been in place when the derogation was originally instated, the scope of the derogated use would have been narrower from the start of the derogation, therefore reducing the potential number of uses allowed.

Under **Article 68(2)**, restrictions are implemented by the Commission to prevent the exposure of consumers to carcinogenic, mutagenic, and reprotoxic (CMR) substances. The scope of the restriction (including derogations) is based on discretion rather than clear guidance or criteria, making it difficult to compare to the essential use criteria. Information which may be considered for derogations from restrictions of substances in articles is suggested in a 2014 CARACAL paper which outlines criteria to help guide the Commission in considering Article 68(2) restrictions.[157] This includes suggestions to consider derogations where the relevant markets are characterised by fast moving and disruptive innovation, a high number of SMEs, limited financial capacity, or where the substance is a critical material or found in critical uses. Aside from the last point on critical uses, the considerations differ substantially to the essential use criteria.

In existing restrictions under Article 68(2), there are some exemptions from the scope of restriction in articles which would likely not be exempted under the essential use concept (with noted uncertainty as essentiality has not been assessed). For example, the restriction of CMRs in textiles and clothing does not apply to: accessories not related to clothing, such as jewellery, glasses and sunglasses; curtains; wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners; textile lampshades and wall decorations; napkins and table linen; filling materials in chairs, armchairs and sofas; clothing, related accessories or footwear made exclusively of natural leather, fur or hide; non-textile fasteners or decorative attachments such as buttons, zips etc.[158] These exclusions were introduced to be addressed in future restrictions. It is difficult to conclude whether the essential use concept would allow fewer or more derogations overall given that the current reasons for derogation are based on Commission discretion.

On the other hand, for Article 68(2) restrictions of substances and mixtures, in particular for consumers, very few derogations have been granted. It is unclear what proportion of uses of CMR

[157] European Commission, (2014). 16th Meeting of Competent Authorities for REACH and CLP (CARACAL)10-11 November 2014. CA/102/2014. November 2014.
[158] Commission Regulation Commission Regulation (EU) 2018/1513 of 10 October 2018 amending Annex XVII to REACH Regulation as regards certain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B (entry 72 of REACH, Annex XVII). European Commission, (2018). Explanatory Guide on the Restriction on CMRs 1A and 1B in Textiles and Clothing. Retrieved on 2022-11-23 at: https://ec.europa.eu/docsroom/documents/32006

substances and mixtures could be assessed as essential for society and therefore whether the essential use concept would influence the frequency of such derogations.

Overall, the assumption is made that under Article 68(1) fewer uses of substances would be allowed under the essential use concept, based on the observation that current restriction derogations could be set based on greater consideration of economic factors. The essential use concept would most likely justify only a sub-set of uses which are currently justified based on SEA. For Article 68(2) it is less clear how the essential use concept would influence the number of uses derogated from restriction under Article 68(2), however, it is suspected that the essential use concept could reduce the number of derogations for substances in articles because clear criteria would replace the current rationale which relies on discretion by the Commission.

Assumption 2 – The essential use concept would result in a reduced proportion of authorisations in comparison to the baseline.

The current REACH authorisation process allows uses of substances via the SEA or adequate control route for authorisation.

The SEA route shares similar elements with the essential use concept as it includes consideration of the lack of alternatives. However, the SEA route also looks at socio-economic benefits from the use, including but not only for, the applicant(s) and compares them with risk to human health and the environment arising from the use of the substance. The essential use concept would not justify derogations for uses based purely on socio-economic benefits, including for the applicant.

Furthermore, the scope for analysis of alternatives differs between the essential use concept and the baseline. Under the essential use concept, availability of alternatives should be considered from a societal point of view, and so authorisations would only be granted if alternatives are not available *in general* (as concluded in Part B of this report) (i.e., if alternatives are not available across the EU to support continuation of the service provided to society). In contrast, under the baseline, authorisations may still be granted via the SEA route if alternatives are available *in general*, but not technically or economically feasible *for the applicant*, provided the applicant has submitted a substitution plan. This was clarified by the EU General Court judgement in Case T-837/16[159] and has only applied in a limited number of cases so far.

The baseline also includes provisions for authorisations to be granted where risk is adequately controlled (however, this route has not been widely used in the past to authorise uses because for most of the substances that are subject to authorisation, no safe threshold can be demonstrated, and even for substances with a threshold, in certain cases the applicants had difficulties in demonstrating that their exposure/emissions from the use were adequately controlled). Depending on the sub-option, the essential use concept would not authorise uses based on the adequate control considerations.

[159] European Commission (2020), Assessment of alternatives: Suitable alternative available in general & requirement for a substitution plan. May 2020.

Case study – hexabromocyclododecane (HBCDD) [160]

HBCDD was authorised for use as a flame retardant additive in expanded polystyrene. This case study has been included to exemplify how the evidence / argumentation for justifying authorisations under the baseline (SEA route for authorisation) differs to the evidence / argumentation which would be required to justify continued use under the essential use concept. The differences are explained below in terms of assessment of benefits, analysis of alternatives, and minimisation of the use, emissions, and exposure.

1) Assessment of benefits

The cost-benefit analysis undertaken by the applicant and assessed by SEAC (to demonstrate that benefits of continued use outweigh the risks) included large uncertainties and focused only on the socio-economic impacts on manufacturers from loss in production of expanded polystyrene with flame retardants. In comparison, the essential use concept would not justify an authorisation based purely on economic factors, and instead would have required an assessment of the necessity of the use for health and safety and/or criticality for the functioning of society.

2) Analysis of alternatives

The use of HBCDD as a flame retardant in expanded polystyrene was authorised based on non-availability of one suitable alternative (pFR or phenol-formaldehyde resin, a copolymer of styrene and butadiene) *to the applicants.* The SEAC opinion shows that other alternatives were already technically and economically feasible for other companies. These alternatives included PUR/PIR (polyurethane rigid foam and polyisocyanurate) and mineral wool, which were available and commonly used on the market. Furthermore, although the availability of pFR to the applicants was not guaranteed, the alternative was already used by other actors at the time, hence, retrospectively, this could be seen as having suitable alternatives available *in general*. Nevertheless, this case preceded the case law (Case T-837/16) and SEAC's opinion focussed on the availability and technical and economic feasibility *for the applicants*, concluding that the availability of pFR to them was not guaranteed. In contrast, the essential use concept would require that availability and suitability *in general* were considered (e.g. whether the alternatives are sufficiently available to avoid loss of the essential use to society as a whole, rather than to individual applicants).

3) Minimising the use, emissions, and exposure

Due to a lack of information provided by the applicant, RAC was unable to conclude on the risk and, in turn, to confirm whether the remaining risk is reduced to as low a level as is technically and practically possible. The essential use concept would not have justified authorisation in the absence of this information, as it was insufficient to ensure that all steps were being taken to minimise the use and any associated emissions of and exposure to the controlled substances.

It must be considered whether any authorisations which could be justified by the essential use concept would not be justified under the current reasons used to justify authorisations. Theoretically, if a use is necessary for health, necessary for safety, or critical for the functioning of society, this should materialise in SEA and the use would be allowed under current reasoning. Many authorisations have been granted in the past for uses related to health and safety. For example, uses of Cr(VI) are authorised for corrosion inhibition in surface treatment of aeroplane

[160] Committee for Risk Assessment, RAC and Committee for Socio-economic Analysis, SEAC (2015). Opinion on an Application for Authorisation for Hexabromocyclododecane (HBCDD), alphahexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane Use: Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications). ECHA/RAC/SEAC: AFA-O-0000004949-56-11/D.

parts to ensure safety[161] and uses of octyl- and nonylphenol ethoxylates have been authorised for the production of medicinal active substances as well as for uses in in vitro diagnostic kits.[162]

There is a possibility that the essential use concept could encourage authorisations of uses which might not be sought under the baseline. The current data collection and analysis required to demonstrate that socio-economic benefits outweigh risks do not allow predictability of whether uses may be authorised. However, if the essential use criteria make it clear what is essential for society without complex analysis (e.g. no economic analysis) but rather based on political judgment, this may encourage applications. This possibility is highly uncertain, and it seems from past authorisations that important uses likely to meet the essential use criteria would be authorised under the baseline. Further, as noted in the section above on restrictions, the decision by the Commission based on the essential use criteria on whether to authorise a use should ensure that only truly "essential" uses for society are granted authorisations, which should ensure that authorisations are exceptional.

Overall, it seems that essential uses are likely to be authorised / derogated from restrictions under both the baseline and the options for implementing the essential use concept. Non-essential uses would not be authorised under the essential use concept but could be authorised under the current authorisation process based on the SEA and adequate control routes. This underpins the conclusion that a smaller proportion of uses could be authorised based on criteria of essentiality in comparison to the rationale under the baseline, although this scale of reduction is not possible to quantify.

Assumption 3 – The essential use concept would encourage substitution of the most harmful chemicals to a greater degree than under the baseline.

As the essential use concept would be expected to allow a smaller proportion of uses to be derogated/authorised (assumptions 1 and 2), it would encourage substitution of the most harmful chemicals for uses which can no longer be derogated/authorised. Where alternatives are already available, substitution would be highly likely to take place. For uses where alternatives are not available, this is likely to encourage research and development for alternatives.

For derogated/authorised uses, both the baseline and the essential use concept include measures to encourage substitution. Under the baseline, authorisations are time-limited, while derogations from restrictions may be time-limited or unconditional. The frequency of unconditional restriction derogations is unknown, but as the essential use concept would impose time limits for all derogations (according to Part B of this report), it would be expected to encourage substitution to a greater degree.

The main difference from the baseline in terms of pressure to substitute is the essential use concept requirement for industry to demonstrate that appropriate effort is being made to substitute the use. Current authorisations only require industry to show that they *plan actions* to substitute where suitable alternatives are available (not in other instances) and do not require demonstration that appropriate effort is being made *in practice*, e.g. through monitoring, reporting etc. Under restriction derogations, substitution plans are not required, and only in some cases can derogations be progress-limited (where the derogation is contingent on industry showing that progress in the research on and development of alternatives is actually being made).

Therefore, the essential use concept could result in more substitution due to:

[161] ECHA, (2020). Chromium trioxide downstream user notifications of REACH authorised uses. Retrieved on 2022-11-23 at: https://www.echa.europa.eu/documents/10162/5d1a1ac9-1fde-3c48-3f36-bdcf26c19c45

[162] European Commission, (2022). Summary of European Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Retrieved on 2022-11-23 at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022XC0323(04)&from=EN

- Encouraged substitution of the most harmful chemicals in non-essential uses which could otherwise be derogated/authorised under the baseline (e.g. for economic reasons).
- Time limits for all derogations from restrictions (rather than most derogations under the baseline).
- The requirement for all authorisations and derogations from restrictions to be contingent upon industry demonstrating appropriate effort to substitute.

Assumption 4 – The essential use concept would increase the pressure to minimise the use, emissions, and exposure of uses which could be derogated or authorised, in comparison to the baseline.

Under the baseline, authorisations must specify the conditions of the authorisation, which may include requirements for additional risk management measures. Authorisation holders must also ensure that the exposure is reduced to *as low a level as is technically and practically possible*, in accordance with Article 60(10). This is similar to the essential use concept requirement to ensure all steps are taken to minimise emissions and exposure as concluded in Part B of this report.

In derogations from restrictions under the baseline, there is no formal requirement to minimise a derogated use and associated emissions, exposure, and risk. However, derogations may include provisions such as concentration limits or other conditions of use. For example, the guidance on preparation of restriction dossiers presents a case involving the use of a substance in hydraulic fluids where there are no available alternatives but the substance presents unacceptable risks to the environment and concludes that the use could be derogated with conditions[163]. Given that the essential use concept would introduce a formal requirement to minimise the use, exposure and emissions, it could result in increased pressure to minimise the risks associated with the use, however, this is uncertain at this stage.

It is difficult to validate this assumption with the evidence available to the project team. However, in theory, the essential use concept includes specific requirements to ensure that the use, emissions and exposure of derogated/authorised uses are minimised, in contrast to the baseline, which includes no explicit requirement for this, except for Article 60(10) on authorisation.

11.3.2 Uncertainties

The following uncertainties are described below, to explain the theoretical nature of this assessment.

- Uncertainty 1 – The impacts of the most harmful chemicals, which the essential use concept aims to address, are largely unknown.
- Uncertainty 2 – The number and identity of uses and substances to be impacted by the essential use concept are unknown.

Uncertainty 1 – The impacts of the most harmful chemicals, which the essential use concept aims to address, are largely unknown

Human health and environmental impacts cannot be accurately predicted because the essential use concept would target the most harmful chemicals in the context of both generic and specific risk assessment from a life cycle perspective. For example, most available exposure data typically fails to account for the full life cycle of chemicals (which is particularly challenging for persistent and bioaccumulative chemicals). Furthermore, many of the most harmful chemicals do not have safety thresholds. ECHA notes that for persistent and bioaccumulative chemicals, long term effects may occur even if laboratory testing demonstrates no toxicity, since unpredictable levels may be

[163] European Chemicals Agency, ECHA (2007). Guidance for the preparation of an Annex XV dossier for restrictions. (EC) No 1907/2006. December 2006.

reached in humans or the environment over extended time periods (hence why vPvB substances are targeted under REACH).[164]

Evidence from observational studies (directly monitoring impacts on humans and the environment from chemicals) has been described in this project, however, this type of evidence is limited in strength and is typically limited to well-known chemicals which have already been regulated.

Uncertainty 2 – The number and identity of uses and substances to be impacted by the essential use concept is unknown.

VVA (2022) estimated that over 1,200 substances are currently, or suspected to be, most harmful chemicals[165] (pending the final results of the study which are not published at the time of writing), therefore an extremely large amount of data would be required to accurately predict the impacts of these substances on the environment and human health. Furthermore, the essential use concept would impact these substances in a complex way by justifying the allowance of some uses and not others (although specifically which ones is unknown at this stage). Most substances have a range of uses, therefore predicting the impacts of the derogations of multiple uses for each of 1,125 substances would be highly complex.

Under this project, two case studies for REACH substances were investigated in Task 3 (Appendix B). Both of these showed potential ways the essential use concept could have made the decisions to derogate/authorise uses easier (described later in regard to administrative costs), but do not indicate differences in which uses would be derogated under the baseline and which would be derogated under the essential use concept. The uses subject to derogations would be highly substance- and use-specific.

11.4 Environmental impacts

The following impacts were explored in terms of costs and benefits:

- Impacts directly on the environment from use, exposure to and emissions of the most harmful chemicals;
- Impacts on the circular economy;
- Impacts from regrettable substitution of the most harmful chemicals; and
- Impacts from substitution with less sustainable alternatives.

The analysis showed that for each of these impacts, the net consequence of implementing the essential use concept in comparison to the baseline (current rationale for derogating/authorising uses of the most harmful chemicals) is expected to be positive. This is based on assumptions set out in section 11.3 above and further explained in the below sections.

11.4.1 Direct impacts on the environment from use, exposure to and emissions of the most harmful chemicals

Impact categories (BRT Tool #18): Quality of natural resources; biodiversity; animal welfare; likelihood or scale of environmental risks; sustainable development.

Type of impact: Very positive

Description: The essential use concept would allow uses of the most harmful chemicals to be derogated from restrictions or authorised **only when they are essential for society**. Overall, this

[164] European Chemicals Agency, ECHA (2017). Guidance on Information Requirements. ECHA-17-G-12-EN. June 2017.
[165] Valdani Vicari & Associati, VVA (2022) Workshop on the extension of the generic approach to risk management under the REACH Regulation. 21 March 2022 Background paper

would be expected to have a **net reduction in uses of the most harmful chemicals** in comparison to the baseline, through reducing the number of uses which could be allowed, decreasing the intensity of allowed uses, and increasing the pressure to substitute all uses (see assumptions set out in section 11.3). Reductions in uses of the most harmful chemicals would lead to reduced human exposure, emissions and environmental exposure, therefore limiting the impacts of chemicals on the natural environment (e.g. impacts on soil, water, and air quality as well as impacts on species, ecosystems and biodiversity).

For essential uses – There is no predicted difference between the baseline and implementation of the essential use concept because the baseline would allow essential uses based on current rationale, i.e., if use of a substance is necessary for health/safety or critical for the functioning of society, socio-economic analysis would most likely show that socio-economic benefits are high compared to the risks. This is based on assumptions set out in section 11.3.

For non-essential uses – The baseline would allow some (an unknown proportion of) non-essential uses, which could not be justified by the essential use concept. For example, uses which are not critical for the functioning of society or necessary for health/safety but have socio-economic benefits which outweigh risks or where alternatives are available in general but not for the authorisation applicant. This is based on assumptions set out in section 11.3.

Significance: Chemicals with certain hazard properties can result in negative impacts on the environment due to emissions over the chemical life cycle, from production to use and disposal/re-use. The most harmful chemicals, which would be targeted by the essential use concept, are hazardous to humans and/or the environment and may be of environmental concern due to the following hazard properties: persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); and endocrine disrupting properties.

Impacts of these types of chemicals have been demonstrated by a large volume of studies over decades. For example:

- The chemical tributyltin has demonstrated the impacts that endocrine disrupting, PBT, and vPvB substances can have on the environment, as the substance meets all hazard classifications. Tributyltin is present in aquatic environments primarily due to its historic use as an antifouling agent on ship hulls. In 2018, it was detected in 663 EU water bodies above the environmental quality standards threshold[166]. Tributyltin causes reproductive and sexual health impacts on bacteria, phytoplankton, plants, crustaceans, fish, and mammals. Impacts range from growth inhibition, respiration disruption, decreased productivity, developmental toxicity, endocrine disruption (e.g. imposex and masculinisation), reproductive toxicity (e.g. sterility), cardiovascular toxicity, and neurotoxicity (Sousa et al., 2014)[167]. Some invertebrate communities are still recovering from population level impacts even after the international ban on tributyltin in 2008[168,169].
- Polybrominated diphenyl ethers (PBDEs) have also exemplified effects that endocrine disrupting, PBT and vPvB substances can have on the environment. For example,

[166] European Environment Agency, EEA (2018). European waters assessment of status and pressures 2018. No 7/2018.
[167] Sousa, A.C., Pastorinho, R., Takahasi, S., Tanabe, S., (2014). History on organotin compounds, from snails to humans. *Environmental chemistry letters,* 12(1), 117-137.
[168] International Maritime Organization, IMO. International Convention on the Control of Harmful Anti-fouling Systems on Ships. Retrieved on 2022-11-23 at: https://www.imo.org/en/About/Conventions/Pages/International-Convention-on-the-Control-of-Harmful-Anti-fouling-Systems-on-Ships-(AFS).aspx translated into EU law by Commission Regulation (EC) No 536/2008
[169] Matthiessen, P., (2019). The impact of organotin pollution on aquatic invertebrate communities—are molluscs the only group whose populations have been affected? *Current Opinion in Environmental Science & Health,* 11, 13–20.

negative impacts (decreased taxonomic and functional diversity) on macroinvertebrates have been observed in sites contaminated with PBDEs.[170]

Further evidence of negative impacts on the environment from chemicals with these hazard properties can be found through considering previous restrictions and additions to the Candidate List under REACH, which are justified by the potential impacts of certain substances on the environment and human health. For example, ECHA estimated that emissions of over 95,000 tonnes of substances of environmental concern would have occurred if REACH Article 68(1) restrictions were not in place.[171]

While the above evidence describes substances for which regulatory action has already been taken, it must be noted that environmental exposure to hazardous chemicals continues to persist despite existing regulations and risk management measures implemented by industry and professional users of chemicals. For example, an estimated 65% of European water bodies are "insufficiently protected" from chemicals according to a recent study.[172] This demonstrates the scope for improving the stringency of restrictions of chemicals to mitigate environmental exposure.

Ideally, this project would investigate the extent to which environmental impacts of chemicals can be attributed to the most harmful chemicals (as defined in the CSS as the target of the essential use concept), as well as the extent to which the essential use concept could decrease these impacts based on assumptions set out in section 11.3 (that the essential use concept would result in fewer uses of the most harmful chemicals). To fully examine the benefits expected to the environment, the following information would be required:

- Proportion of substances and uses expected to be derogated from restriction or authorised under the baseline and the same for the essential use concept options.
  - Note, the number of substances qualifying as the 'most harmful chemicals' is predicted to be over 1,200 (VVA, 2022) (pending the final results of the study which are not published at the time of writing)[173]. The total number of uses has not been estimated, nor has the number or proportion of uses expected to be justified for derogation/authorisation under the baseline and under the options for the essential use concept.
- Emissions and exposure patterns associated with non-essential and essential uses (for society) of the most harmful chemicals. For example, the benefit would be greater if more wide dispersive uses do not meet the essential use criteria and are therefore restricted (in contrast to low dispersive uses).
  - VVA (2022) conducted a "use mapping" exercise, demonstrating the use of the most harmful chemicals in various product categories. As above, the final results of the study are pending.
- Information related to risks and impacts of the uses of substances for which derogations would be justified under the baseline and under the options for implementing the essential use concept. For example, expected changes in impacts based on exposure modelling or monitoring and environmental safety thresholds (e.g. PNECs and DMELs).

[170] Windsor, M., Pereira, M. G., Tyler, C.R., Ormerod, S.J., (2019) Persistent contaminants as potential constraints on the recovery of Urban River Food Webs from gross pollution. *Water Research*, 163, 114858.
[171] European Chemicals Agency, ECHA, (2021). Costs and benefits of REACH restrictions proposed between 2016-2020. ECHA-21-R-02-EN. February 2021.
[172]Posthuma, L., Van Gils, J., Zijp, M.C., Van de Meent, D., de Zwarts, D., (2019) Species sensitivity distributions for use in environmental protection, assessment, and management of aquatic ecosystems for 12386 Chemicals. *Environmental Toxicology and Chemistry*, 38(4), 905–917.
[173] Valdani Vicari & Associati, VVA (2022) Workshop on the extension of the generic approach to risk management under the REACH Regulation. 21 March 2022 Background paper]

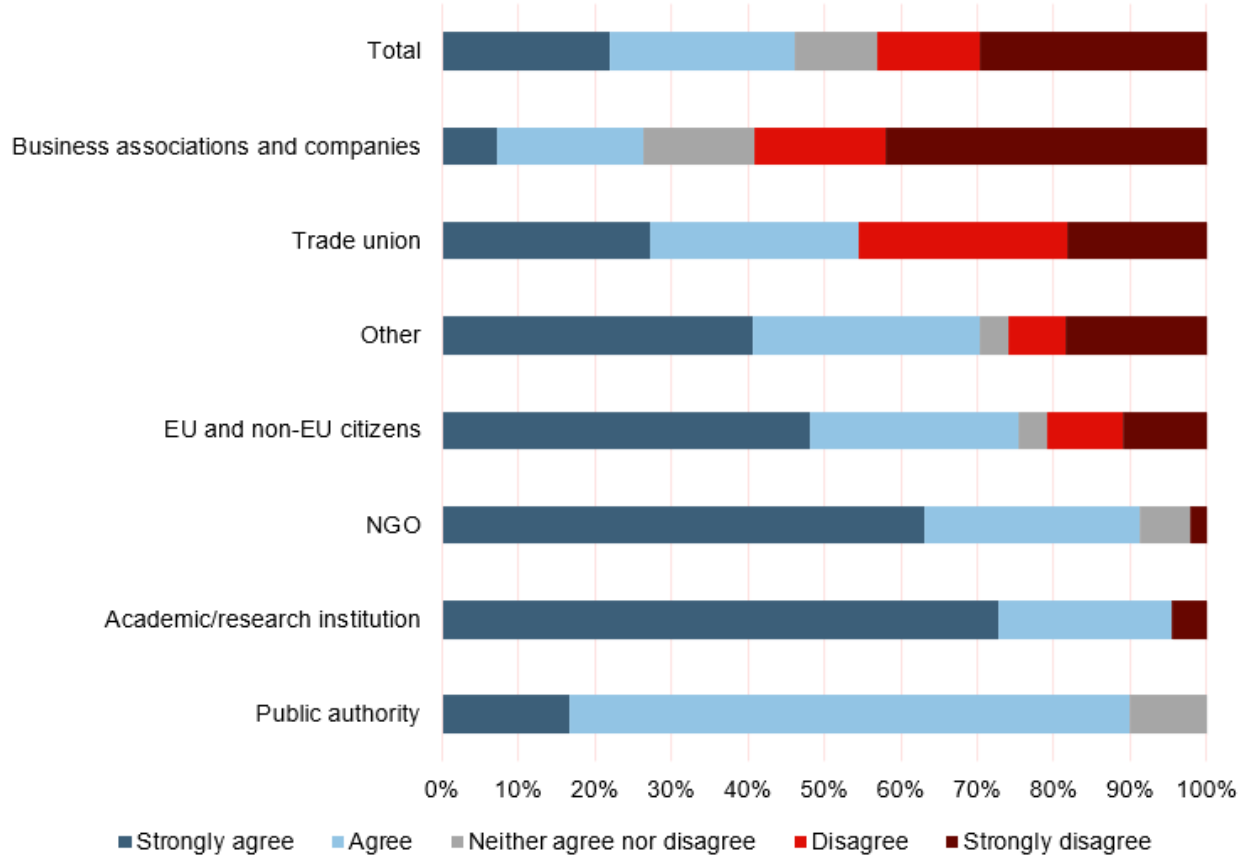
Despite studies looking at the impacts of individual chemicals / groups of chemicals, and in some cases mixtures of chemicals, information on the cumulative impacts of all most harmful chemicals, as well as the cumulative impacts of non-essential and essential uses (for society) of these substances, is lacking. As well as a lack of studies and evidence on this, the fundamental limitations to understanding these impacts (lack of safe thresholds, unpredictable human and environmental exposure over time, inability of laboratory tests to demonstrate all toxic effects) are further set out in section 11.3.

In the absence of this information, positive impacts to the environment are assumed because of the increased stringency of the essential use concept in comparison to reasons for derogations / authorisations under the baseline (see assumptions under section 11.3) and because of the hazard properties of the most harmful chemicals which indicate their potential for causing harm. Reduced uses of the most harmful chemicals would mean a reduced likelihood of environmental exposure. For some uses (consumer uses and uses which expose vulnerable groups), generic exposure considerations are further indicative of potential benefits from the essential use concept.

It is also worth noting that most stakeholder types (except for industry representatives) who responded to the public consultation for the targeted revision of REACH[174] predicted that introduction of the essential use concept could increase protection against the most harmful chemicals and lead to benefits for the environment (Figure 11.1). This suggests that implementation of the essential use concept would be expected to be beneficial to the environment.

[174] European Commission, (2022). Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment. Retrieved on 2022-11-23 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/public-consultation_en

Figure 11.1 Stakeholder responses to the public consultation on the revision of REACH question "do you agree that applying an essential use concept specifically under REACH could lead to benefits for the environment?"



Likelihood: Very likely – implementation of the essential use concept would be expected to reduce the number and intensity of uses of the most harmful chemicals in comparison to the baseline (based on the assumptions set out in section 11.3). A reduction in number and intensity of uses of the most harmful chemicals is highly likely to translate to a reduction in negative impacts, given that the hazard properties of the most harmful chemicals are of high concern and can result in negative impacts even when specific risk assessment indicates low risk (i.e., already at very low exposure/emissions). The unknown exposure and risks of uses to be targeted by the essential use concept prevent any further conclusions on the predicted scale of impacts.

11.4.2 Impacts on the circular economy

Impact categories (BRT Tool #18): Sustainable consumption and production; efficient use of resources; waste production, generation and recycling; sustainable development.

Type of impact: Positive

Description: The essential use concept is expected to allow uses of the most harmful chemicals otherwise banned only when essential for society, lowering so the number of their uses that are allowed/derogated under the baseline. Overall, this is expected to have a **net reduction in uses of the most harmful chemicals** in comparison to the baseline, through reducing the number of uses which could be derogated, decreasing the intensity of derogated uses, and increasing the pressure to substitute all uses (see assumptions set out in section 11.3). This would reduce the presence of

these chemicals in materials and products, positively contributing to the transition to non-toxic material cycles and a functioning market for safe secondary raw materials.

There is a possibility the essential use concept could hinder the transition to sustainable material cycles, depending on the level of performance of alternatives. In some cases, alternatives may have lower performance in comparison to the most harmful chemical, which could result in reduced product life span and more frequent replacement, resulting in the consumption of more materials. This is covered in the broader section on sustainability below (11.4.4).

Significance: The presence of harmful chemicals in products results in the accumulation of chemicals in recycled materials and products over time, which may result in human and environmental exposure. Accumulation of chemicals in materials and products has been demonstrated in several studies, for example, showing the occurrence of lead, PBDEs, phthalates and bisphenol-A in recycled plastics.[175] Some of the most harmful chemicals are persistent, increasing the probability that they could accumulate in materials over time, therefore increasing the likelihood of this problem.

As well as resulting in further exposure to certain chemicals, this can limit the transition to a circular economy as downstream customers may reject materials as feedstock to production processes if they are contaminated by hazardous substances[176] (a rejection which has positive impacts regarding chemical exposure, but negative impacts regarding waste and resource efficiency). The EU aims to reduce the problem of chemical contamination of recycled materials, e.g. through initiatives such as the SCIP database[177] and the circular economy action plan[178].

It is unclear specifically how limiting the most harmful chemicals are to current recycling practices and to what extent they lead to further emissions of the most harmful chemicals, however, there is some evidence that over 40% of recycled materials contain (hazardous) contaminants.[179] Reduction of use of the most harmful chemicals as a result of the essential use concept would reduce the scale of this problem.

Likelihood: Very likely – based on the assumption that the essential use concept would reduce the use of the most harmful chemicals (section 11.3), the concept is very likely to result in a reduced presence of most harmful chemicals in both raw materials and secondary materials. This is expected to positively impact the transition to a circular economy and reduced exposure from recycled materials.

[175]Turner, A. and Filella, M., (2021). Lead in plastics – recycling of legacy material and appropriateness of current regulations. *Journal of Hazardous Materials,* 404, 124131. ,Strakova, J., Digangi, J., Jensen, G., Petrlik, J., Bell, L., (2018). Toxic Loophole: Recycling Hazardous Waste into New Products. Pivnenko, K., Eriksen, M.K., Martin-Fernandez, J.A., Eriksson, E., Astrup, T.F., (2016). Recycling of plastic waste: Presence of phthalates in plastics from households and industry. *Waste Management*, 54, 44–52.

[176] Human Biomonitoring for Europe, HBM4EU (2022). Chemicals in a circular economy: Using human biomonitoring to understand potential new exposures.

[177] European Chemicals Agency, ECHA (2022). SCIP. Retrieved on 2022-11-23 at: https://echa.europa.eu/da/scip

[178] European Commission, (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, a new Circular Economy Action Plan, For a cleaner and more competitive Europe. COM(2020) 98 final. 11th March 2020.

[179] E.g., Eriksen, M.K., Damgaard, A., Boldrin, A., Astrup, T.F., (2018). Quality Assessment and circularity potential of recovery systems for household plastic waste. *Journal of Industrial Ecology*, 23(1), 156–168. ; Vápenka, L., Vavrouš, A., Votavová, L., Kejlova, K., Dobiáš, J., & Sosnovcová, J.,(2016). Contaminants in the paper-based food packaging materials used in the Czech Republic. 55. 361-373. ; Turner, A. and Filella, M. (2017). Bromine in plastic consumer products – evidence for the widespread recycling of electronic waste. *Science of The Total Environment*, 601-602, 374–379.

11.4.3 Impacts on the environment due to regrettable substitution of the most harmful chemicals

Impact categories (BRT Tool #18): Quality of natural resources; biodiversity; animal welfare; sustainable consumption and production; likelihood or scale of environmental risks; sustainable development.

Type of impact: Neutral – positive.

Description: Regrettable substitution describes scenarios where harmful substances are banned and subsequently substituted by alternatives which cause a similar or higher level of harm to the environment and/or human health, which counteracts the environmental (or health) benefits of the ban.

Industry representatives have raised concerns that regrettable substitution may be encouraged by the essential use concept because of the increased pressure to substitute uses of the most harmful chemicals (for both essential uses and non-essential uses).

Section 11.3 explains the assumption that substitution of chemicals in derogated uses would be encouraged more strongly by the essential use concept in comparison to the baseline.

Statistically, if the number of substitutions increases due to the essential use concept, the number of regrettable substitutions would also increase. The essential use concept includes provisions to prevent regrettable substitution (requiring that alternatives should be 'acceptable from the standpoint of environment and health'). However, similar provisions already exist under the baseline. For example, current authorisation requires that alternatives must be suitable under Article 60(4). A suitable alternative must be safer for the environment and human health than the controlled substance.[180]

For authorisations, there may be no difference, given that the provisions under the baseline are similar to the proposed conditions under the essential use concept. However, it is notable that despite the existing provisions under the baseline, regrettable substitution still occurs. For example, the most common substitute for the SVHC trichloroethylene is perchloroethylene, which is toxic to the aquatic environment with long lasting effects and suspected to be carcinogenic.[181] Regrettable substitution may therefore remain a problem for both the baseline and the essential use concept. However, there is potential to improve the situation through implementing the essential use concept, because if *properly enforced*, alternatives must be acceptable from the standpoint of the environment and human health.

The essential use concept may prevent regrettable substitutions of restricted substances because there is no formal requirement under the current restriction process for alternatives to be safer / suitable / acceptable from the standpoint of environment and health. Existing legislation and guidance only show that risks from alternatives should be considered. For example, Annex XV and the existing guidance on preparing restrictions state that the assessment of risks related to the alternative should document whether substitution would result in reduced overall risks to human health and the environment.[182] Material on the ECHA website also explains how to conduct an analysis of alternatives, explaining that all hazards and risks should be assessed.[183]

[180] European Commission, (2020). Assessment of alternatives: Suitable alternative available in general & requirement for a substitution plan.
[181] European Chemicals Agency, ECHA, (2022). Case study: Impacts of REACH authorisation of trichloroethylene. ECHA-22-R-02-EN. March 2022.
[182] European Chemicals Agency, ECHA (2007). Guidance for the preparation of an Annex XV dossier for restrictions. (EC) No 1907/2006. December 2006.
[183] European Chemicals Agency, ECHA (2022). Online training on analysis of alternatives. Retrieved on 2022-11-23 at: https://echa.europa.eu/da/online-training-on-analysis-of-alternatives

Therefore, for restrictions, the essential use concept could reduce regrettable substitution because of the explicit requirement for alternatives to be acceptable from a standpoint of the environment and human health.

Significance: As stated in the 2018 REACH review, Milieu et al. found that 35% of companies responding to consultation have substituted at least one substance with a chemical alternative that was subsequently concluded to be of concern,[184] indicating relatively high prevalence of regrettable substitution, although Maertens et al. (2021) comment that there is an evidence gap surrounding the frequency of regrettable substitutions.[185] As such, it is difficult to know the severity of this problem under the baseline.

The nature of this impact on the environment depends on the proportion of these substitutions which are regrettable and the proportion which are not regrettable, both for the baseline and under the essential use concept. Although this is unknown, it seems logical that most substitutions would not be regrettable given the essential use requirements to ensure acceptability from the standpoint of environment and health.

Likelihood: Low / medium likelihood that the essential use concept could reduce risks of regrettable substitution. Both the baseline and the essential use concept include provisions to deter regrettable substitution. Under the current restriction process, this is limited to guidance (but in practice restriction proposals generally include identification of the risks of alternatives). Therefore, the essential use concept could further reduce regrettable substitution depending on how it is implemented (e.g. legally binding would be more effective) and how it is enforced (to ensure alternatives are acceptable from the standpoint of environment and health).

11.4.4 Impacts on the environment from substitution with (less) sustainable alternatives

Impact categories (BRT Tool #18): Climate; sustainable consumption and production; efficient use of resources; land use; transport and the use of energy; waste production, generation and recycling; sustainable development.

Type of impact: Weakly positive.

Description: Industry representatives raised concerns that the increased pressure to substitute (assumption 3, section 11.3) could result in substitution of the most harmful chemicals with less sustainable alternatives. For example, if alternatives are made from less sustainable materials and feedstocks; if their manufacturing is more resource (e.g. energy, material, land, water) intensive; if the alternative decreases durability of the product (and therefore increases the frequency with which it needs to be repaired or replaced); or if the alternative is less effective and therefore a greater volume of it is required to perform the same function.

While substitution with alternatives that are less sustainable than the most harmful chemicals is possible, no significant driver for encouraging this was identified. On the contrary, the most harmful chemicals are hazardous and therefore pose inherent challenges to sustainability, e.g. in terms of achieving a toxic free environment, therefore it is likely that alternatives would be more sustainable at least in terms of hazardousness (see also the above section on regrettable substitution). Furthermore, the essential use concept requirement for uses to be “acceptable from the standpoint of human health and the environment” should, to a certain extent, take into account the overall health and environmental impacts of the alternative, not only from the perspective of chemical

[184] European Commission, (2018). Commission General Report on the operation of REACH and review of certain elements. SWD(2018) 58 final. 5th March 2018.
[185] Maertens, A., Golden, E. and Hartung, T., (2021). Avoiding regrettable substitutions: Green Toxicology for Sustainable Chemistry. *ACS Sustainable Chemistry & Engineering*, 9(23), 7749–7758.

hazards, therefore reducing the likelihood of substitution of less sustainable chemicals/materials/products.

Under the baseline, there are no legal provisions for alternatives to be sustainable, however guidance on the ECHA website recommends that identification and assessment of alternatives should consider the wider effects of substitution, including sustainability across the lifecycle of the alternative.[186] The same (or at least similar) guidance on the identification and assessment of alternatives would apply under all options for introducing the essential use concept.

Significance: As noted above, it is more likely for the essential use concept to encourage substitution with alternatives which are more sustainable than the most harmful chemicals. This could benefit climate change and circularity, in terms of energy consumption, greenhouse gas emissions, land use, water use, material use, waste, limited recyclability etc.

Given that current production of chemicals is typically energy and resource intensive (according to the CSS), there is potential for substantial benefits to the environment if substitution with more sustainable chemicals is encouraged.

In response to an ECHA consultation, 15% of companies reported that improved consumer perception of the company's environmental and social sustainability was a benefit from substitution, indicating that substitution may be likely to have sustainability benefits (although notably, perception does not necessarily reflect real change in sustainability). Ultimately, the main benefit of substitution reported by companies was the reduced emissions of hazardous chemicals,[187] which reflects a positive change in terms of one aspect of sustainability (pollution reduction is a key goal under the EU sustainability agenda set out by the Green Deal). Although this only reflects one aspect of sustainability, it is difficult to predict whether alternatives would be more or less sustainable in terms of other factors, such as energy consumption and land use.

With ongoing developments in identifying safe and sustainable chemicals and materials (e.g. the safe and sustainable by design framework for chemicals and materials[188]), it is likely that identifying alternatives which are acceptable from the standpoint of environment and health would take into account broader sustainability considerations beyond chemical risk. These developments would likely benefit substitution regardless of the essential use concept, however, the increased encouragement to substitute based on the essential use concept, as well as the explicit requirement for alternatives to be acceptable from the standpoint of environment or health, has potential to work synergistically with these developments to result in more substitution with safe and sustainable chemicals, materials, and products.

Likelihood: Medium likelihood that the essential use concept could encourage more sustainable alternatives, based on the existing guidance to encourage sustainability considerations under the baseline, and the potential for the essential use concept to have a stronger influence depending on how it is implemented. This further depends on how 'acceptable' alternative (from the standpoint of environment and health) is defined / interpreted.

11.5 Social impacts

The following impacts were explored in terms of costs and benefits:

- Impacts on human health from use and emissions of the most harmful chemicals;

[186] European Chemicals Agency ECHA, (2022) Substances of concern: Why and how to substitute? Retrieved on 2022-11-23 at: https://echa.europa.eu/da/search-for-alternatives-for-substitution
[187] European Chemicals Agency, ECHA (2020). Impacts of REACH restriction and authorisation on substitution in the EU. ECHA-20-R-09-EN. July 2020.
[188] Joint Research Centre (European Commission), JRC (2022). Safe and sustainable by design chemicals and materials : framework for the definition of criteria and evaluation procedure for chemicals and materials. Publications Office of the European Union.

- Impacts on human health from loss of uses which could be necessary for human health in the future; and
- Impacts on consumer choice and satisfaction with chemical products and related services.

11.5.1 Impacts on human health from exposure to the most harmful chemicals

Impact categories (BRT Tool #18): working conditions, job standards and quality; public health & safety and health systems; food safety, food security and nutrition.

Impact type: Very positive

Description: Benefits to human health from the essential use concept are expected because the concept would be expected to reduce the number of uses of the most harmful chemicals (see assumptions under section 11.3). Subsequently, this would be expected to reduce the likelihood of human exposure (e.g. via the environment and consumer products) and health impacts, e.g. from chemicals which cause cancer, respiratory sensitisation, endocrine disruption, and specific target organ toxicity.

Significance: Under the baseline, impacts on human health from chemicals continue to occur despite existing regulations and risk management measures implemented by industry and professional users of chemicals. For example, the EEA predicted deteriorating trends in chemical pollution and risks to human health and well-being up to 2030.[189]

The scientific literature is rich with studies demonstrating the impacts of individual chemicals or groups of chemicals on human health; however, the cumulative impacts of all uses of the 'most harmful chemicals' (targeted by the essential use concept) are unknown. An assessment of these impacts is limited because of the lack of data on the identity of these substances and the identity of non-essential and essential uses (for society) of these substances, as well as the uncertainties set out in section 11.3 (e.g. the unpredictability of long-term exposure to persistent substances and the inability of laboratory studies to identify long term toxicity effects).

Broadly, the impacts are assumed to be severe, based on evidence of harm from chemicals with hazard properties which qualify them as amongst the 'most harmful chemicals' and evidence that humans are regularly exposed to such chemicals. For example:

- The WHO estimates at a global (not EU-specific) level that 2.1% of disability-adjusted life years (a measure of the burden of disease born by a population) and 3.6% of total deaths are attributed to chemicals.[190] These estimates are based on well-known impacts of some widely regulated chemicals (e.g. cardiovascular disease caused by lead and cancer caused by occupational exposure to arsenic, both chemicals with hazards which would qualify as 'most harmful chemicals'). The 'most harmful chemicals' include a much larger number of substances which are known to have potential to negatively impact health or the environment.
- In the EU, the health burden resulting from most cancers, neurodevelopment, and reproductive health continues to rise in the EU despite existing chemical regulation.[191] Importantly, these health endpoints are linked with the most harmful chemicals,

[189] European Environment Agency, EEA (2019). The European environment — state and outlook 2020, Knowledge for transition to a sustainable Europe. TH-04-19-541-EN-N.
[190] World Health Organisation, WHO (2021). The public health impact of chemicals: knowns and unknowns - data addendum for 2019. Retrieved on 2022-11-23 at: https://www.who.int/publications/i/item/WHO-HEP-ECH-EHD-21.01
[191] Amec et al., (2017). Study on the cumulative health and environmental benefits of chemical legislation.

although they are also influenced by other risk factors and variables which makes it difficult to determine the significance of the influence of the most harmful chemicals.

- There is a large body of evidence from biomonitoring and modelling to indicate that humans are exposed to the most harmful chemicals. For example, human biomonitoring of over 2,000 pregnant women (mostly in the EU) showed that 75% of 54 endocrine disruptors (EDCs) tested were detected in the majority of samples.[192] Further evidence on exposure has been gathered under the European human biomonitoring initiative (HBM4EU), for example, showing the exposure to substances associated with health effects such as phthalates, PFAS and cadmium.[193]

The policy options for the reform of restriction and authorisation indicate that the essential use concept could be used to justify derogations for professional and consumer uses. Therefore, there is potential for the essential use concept to result in benefits to both workers and consumers by reducing the proportion of uses derogated (see assumptions under section 11.3).

VVA (2022) estimated that over 1,200 substances could be identified as the 'most harmful chemicals (pending the final results of the study which are not published at the time of writing)[194], and therefore the essential use concept has potential to impact a large number of substances by only allowing justification of use where essential for society. However, the number, identity, exposure patterns, and risks of each use affected by the essential use concept in comparison to the baseline is unknown.

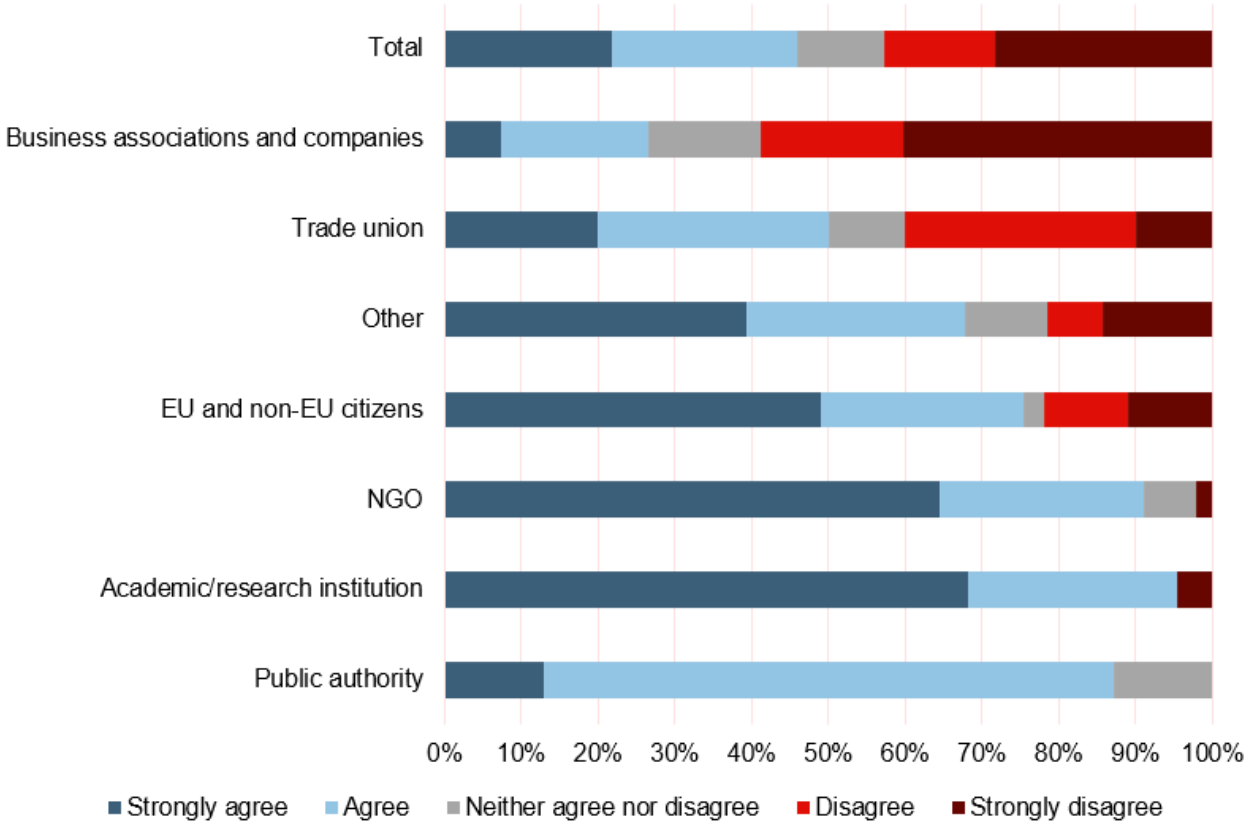
Previous estimations of the monetary value of human health benefits from chemicals legislation (broadly, with no relation to the essential use concept) have been of the order of several billion euros. For example, Amec et al. (2017) suggested that reduced exposure (linked to workplace legislation) to just one carcinogen, hexavalent chromium, avoided 800 deaths (with a monetary valuation of €4 billion) from 1995 – 2010.[195] Overall, changes in REACH have the potential to result in very large impacts to human health, for example, ECHA estimated that 12 restrictions produced health benefits for over 7 million consumers and workers, corresponding to around €2.1 billion per year between 2016 and 2020.[196]

ECHA produced a report on costs and benefits of restrictions in 2021, however, this does not cover the human health costs of derogations[197], which would be relevant to assess the impacts of the essential use concept. Specific evidence of the health impacts of the uses of the most harmful chemicals which would be justified or not justified for derogation or authorisation by the essential use concept is lacking because of lack of information on which substances and uses would be affected by the concept. However, significant positive impacts are assumed based on the observed current exposure to and negative impacts of chemicals (e.g. those with hazard properties which qualify them as the most harmful chemicals) and the assumption that the essential use concept would reduce the number of uses of these substances and encourage the overall phasing out of the most harmful chemicals. Notably, despite the assumptions and uncertainties, there is broad consensus among stakeholders (except from industry representatives) that the essential use concept could increase protection against the most harmful chemicals and lead to benefits for human health (Figure 11.2). Overall, the essential use concept is intended to limit the proportion of

[192] EDC-MixRisk (2019), Policy brief. Retrieved on 2022-11-23 at: https://edcmixrisk.ki.se/wp-content/uploads/sites/34/2019/03/Policy-Brief-EDC-MixRisk-PRINTED-190322.pdf
[193] Human Biomonitoring in Europe, HBM4EU (2022). HBM4EU Final Conference. Retrieved on 2022-11-23 at: https://www.hbm4eu.eu/result/hbm4eu-final-conference/
[194] Valdani Vicari & Associati, VVA (2022) Workshop on the extension of the generic approach to risk management under the REACH Regulation. 21 March 2022 Background paper
[195] Amec *et al.,* (2017). Study on the cumulative health and environmental benefits of chemical legislation.
[196] European Chemical Agency, ECHA (2021). Costs and benefits of REACH restrictions proposed between 2016-2020. ECHA-21-R-02-EN. February 2021.
[197] European Chemicals Agency, ECHA (2021). Costs and benefits of REACH restrictions proposed between 2016-2020. ECHA-21-R-02-EN. February 2021.

derogations from restrictions and authorisations of Annex XIV substances which can be made so that the health benefits of restrictions and additions to the Authorisation List are maximised.

Figure 11.2 Stakeholder responses to the public consultation on the revision of REACH question "do you agree that applying an essential use concept specifically under REACH could lead to benefits for human health?"



Likelihood: High – based on the assumptions set out in section 11.3, the essential use concept would reduce the number of derogated or authorised uses of the most harmful chemicals substantially (number unknown). Further, based on evidence of current exposure and impacts from chemicals, benefits to human health are expected from the reduced use of chemicals which are carcinogenic, toxic to reproduction, mutagenic, respiratory sensitising, toxic to specific target organs, and endocrine disrupting.

11.5.2 Impacts on human health from loss of uses which could be necessary for human health in the future

Impact categories (BRT Tool #18): public health & safety and health systems; food safety, food security and nutrition.

Impact type: Very negative

Description: Industry representatives suggested that there could be negative impacts on human health based on a theoretical scenario where non-essential uses may become essential for society in the future. Industry claims that loss of production capacity of substances (due to assessment of their uses as non-essential for society) would prevent or delay response to a change in the environment or society (e.g. emergence of a threat to society) which could mean that a non-essential use becomes essential for society. In cases where unanticipated and rapid changes in

essentiality could occur, e.g. societal emergencies such as disease outbreak or natural disaster, these impacts could be significant.

Significance: REACH has provisions to respond to emergencies (e.g. Article 129 allows Member States to take appropriate provisional measures if they have justifiable grounds for believing that urgent action is essential to protect human health or the environment). Kentin and Kaarto reported in 2018 that only one derogation had been applied for under Article 129 (to ban materials contributing to public exposure to ammonia).[198] This indicates that there has, so far, been a low probability of this impact based on demand for emergency responses (for the baseline and the essential use concept). No evidence relating to current restriction and authorisation was identified, for example, no revocations or repeals of restrictions. Notably, foresight and emergency planning should exist regardless of the implementation of the essential use concept. For example, in any sector, ability to adapt and ensure supply security is important. This is broader than the scope of the essential use concept and relates to preparedness of the EU to respond to emergencies.

Likelihood: Low likelihood that the EU could lose uses of chemicals which would be necessary for health in the future. This risk exists for the baseline except that a greater proportion of uses could be derogated (assumptions set out in section 11.3) so the risk is higher for the essential use concept in comparison to the baseline.

11.5.3 Impacts on consumer choice and satisfaction with chemical products and related services

Impact categories (BRT Tool #18): Given the diverse range of chemical products, their availability could relate to a number of impacts, e.g. culture; education and training, education and training systems; technological development / digital economy; consumers and households; capital movements, financial markets; territorial impacts; innovation; resilience; security of supply; and sustainable development.

Type of impact:

- Weakly negative (consumer choice)
- Weakly positive (consumer satisfaction)

Description:

The loss of non-essential uses may cause negative social impacts because, although not essential for society, uses which provide convenience and societal benefits may be banned. For example, this includes loss of uses which are beneficial to culture, education, digitalisation, innovation, but not necessary for health/safety or critical for the functioning of society. For non-essential uses where there are alternatives, consumer satisfaction may be affected if the alternatives have different levels of performance. This could be negative in some cases where performance is lower, or positive in some cases if performance is higher. It may be more likely for negative impacts because the essential use concept would force substitution which may have been undesirable otherwise.

No evidence to compare this cost to the baseline was identified, e.g. impacts on consumer choice and satisfaction from previous restrictions and authorisations. The impact is assumed to be more significant under the essential use concept sub-options in comparison to the baseline because of the increased stringency of the criteria which would result in a lower proportion of derogations from restriction or authorisations (see assumptions set out in section 11.3). In terms of territorial impacts, loss of certain uses may have different impacts to different sociodemographic groups and geographies, based on differences in culture as well as differences in societal needs (e.g. due to

[198] Kentin, E. and Kaarto, H., (2018). An EU ban on microplastics in cosmetic products and the right to regulate. *Review of European, Comparative & International Environmental Law*. 27(3), 254–266.

climate or other geographic factors). Although this was stated as a concern by industry representatives, limited supporting evidence was identified from contributions from stakeholders or the literature. One stakeholder noted that loss of a use related to air conditioning would have more negative social impacts in southern countries, e.g. due to discomfort or even health-related impacts in hot weather, although no specific example (use of a substance) was provided.

Given that the essential use concept aims to ensure uses which are essential for society may continue, this impact is unlikely to be significant at the societal level. Furthermore, negative impacts on consumer choice may be counteracted over time to some degree by research, development, and uptake of safer alternatives, which would allow consumers to choose safer products.

The withdrawal of non-essential uses of the most harmful chemicals could result in improved consumer satisfaction with chemicals in products/articles concerning safety and sustainability aspects. For example, the study on impacts of REACH on innovation identified that 70% of suppliers of articles responding to consultation had received requests from customers to remove SVHCs from their products.[199] Furthermore, over 80% of Europeans are worried about the impact of chemicals in everyday products, which indicates that positive social impacts would emanate from decreased presence of the most harmful chemicals in consumer products.

Likelihood: For non-essential uses where there are no alternatives, chemical products relying on these uses would be lost from the market. This would decrease consumer choice. Where alternatives are available, the likelihood of impacts on consumer choice is unknown as the probability of alternatives having higher or lower levels of performance is unknown. There may be improvements in consumer satisfaction due to increased product safety and sustainability. As limited evidence was identified from past restrictions and authorisations, impacts on consumer choice and satisfaction may be considered unlikely with some uncertainty.

11.5.4 Social impacts from loss of essential uses

Impact categories (BRT Tool #18): Given the diverse range of chemical products, their availability could relate to a number of impacts, e.g. culture; education and training, education and training systems; consumers and households; resilience; security of supply; sustainable development.

Type of impact: Very negative

Description: Some industry representatives suggested during consultation that limiting the uses of a substance to only essential uses could limit the economic feasibility of production (if only low volumes of a substance are required for essential uses). Under the argument from industry, this could result in entire loss of that production of the chemical in the EU. This could have significant social impacts if there is no possibility to import the substance or the chemical product.

Significance: No evidence of previous cases of industry not being able to continue production of restricted substances for derogated uses was identified. However, the risk may be pertinent if essential uses make up only a small portion of all uses of the substance. For example, if 95% of uses are non-essential for society and banned, the revenue from the remaining 5% of uses may not be sufficient to support operation of the production facility (in terms of energy, staff, upkeep, refurbishment etc.).

Whether this negative impact would outweigh the health benefits from not using the most harmful chemicals will likely vary on a case-by-case basis. It may be difficult to assess whether the loss of a use which is necessary for health but also causes cancer has a net positive or negative social impact.

[199] Centre for Strategy and Evaluation Services, CSES (2015). Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs.

Likelihood: Low / unknown – for essential uses, chemical products and related services may be lost from the EU market if the volume required for the essential use is so low that production is no longer economically feasible. The likelihood may be reduced in some cases where high demand for the essential use allows costs to be absorbed down the supply chain, however, this could result in negative economic impacts, e.g. increased costs to consumers which could decrease consumer satisfaction. The potential economic impacts are further described in the section below (impacts along the supply chain).

11.6 Economic impacts

The following impacts were explored in terms of costs and benefits:

- Administrative costs to authorities;
- Administrative burden to industry;
- Impacts on profits and jobs for chemical manufacturers;
- Substitution costs to industry;
- Costs to industry to minimise the use, emissions and exposure associated with most harmful chemicals; and
- Impacts along the supply chain.

11.6.1 Administrative costs to authorities

Impact categories (BRT Tool #18): Administrative costs

Type of impact: Uncertain

Description: The essential use concept is intended to decrease administrative burden to authorities because the essential use criteria are intended to be simpler than current criteria for authorisations and derogations from restrictions, therefore, decisions on authorisations and derogations from restriction should be easier and quicker, reducing the time and resources required by authorities. However, it remains to be seen if it would in practice be less onerous to demonstrate essentiality of a use than to demonstrate a net socio-economic benefit of a use.

The essential use concept could also discourage applications for authorisations and requests for derogations. For example, if a use is assessed to be non-essential for society, this would be expected to reduce the likelihood of other applicants applying for authorisations or requesting derogations for similar uses. However, it is unclear how industry will respond to the essential use concept and there is a possibility that the proportion of applications received could increase. For example, granting of essential uses could encourage other applicants with similar uses to apply. Some stakeholders from industry responding to consultation predicted that applications would increase. Overall, we consider it more likely for applications to decrease as the essential use concept is more stringent than the criteria under the SEA route under the baseline (assumptions set out in section 11.3), it is also intended to be more predictable, and assessments of non-essentiality should dissuade other applicants from applying for similar uses.

If a lower proportion of applications for authorisations and requests for derogations from restriction are received because the essential use concept dissuades applicants, this would decrease the burden for all authorities involved in related decision-making. Notably, this is sensitive to the above-mentioned uncertainties.

Short term administrative costs from the essential use concept would include time and human resources to develop guidance documents (e.g. from Commission, ECHA); amending legislative text (depending on the policy option); and costs in training people to evaluate essentiality. In

contrast to the baseline, where progress has already been made for existing processes (e.g. existing guidance, legislative text, trained personnel, etc.), short term administrative costs from the essential use concept are expected to be higher.

Long term differences in administrative costs between the baseline and the essential use concept would include time and resources for: evaluating criticality for the functioning of society and necessity for health and safety instead of evaluating risk and benefits through SEA and adequate control (under the baseline); evaluating alternatives (the same under the baseline); costs in staff training over time (the same under the baseline); requesting reviews of the essentiality of derogated uses (the same under the baseline, although frequency may differ).

The involvement of ECHA's scientific committees, RAC and SEAC, would likely change under the essential use concept as described under the policy options in section 10. For example, SEAC would not be required to review socio-economic analysis for uses which can be justified for derogation/authorisation by the essential use concept. Nevertheless, SEAC might still be required to assess the information on alternatives. In addition, it is still not decided which body would be responsible to assess 'necessity for health and safety' and 'criticality for the functioning of society'. Should such assessment be made by an existing Committee or should a new Committee be created ad-hoc, administrative costs would accrue for such activities.

Significance: Under the baseline, authorisations and restrictions have high administrative costs to authorities.

To consider the predicted difference in administrative costs specifically due to the essential use concept, information on the costs of including derogations in restriction dossiers would be required. This is not available as derogations are not set out as a separate activity within restriction proposals. In some previous cases of authorisations, essentiality could have been simpler to prove than socioeconomic benefits outweighing risk. For example, a consortium of companies applied to use hexavalent chromium compounds in the aerospace sector for anti-corrosion in order to ensure the safe operation and reliability of aircrafts and spacecrafts. In this case, the use is clearly necessary for safety (a conclusion which is easy to draw from considering the use, without requiring the data and analysis needed under the baseline to show that socio-economic benefits outweigh risks from use). However, both the baseline and the essential use concept would require analysis of alternatives, which could be responsible for a larger share of the overall administrative costs.

In general, the essential use concept could help to reduce administrative costs which arise from current difficulties and uncertainties related to authorisation. For example, broad use descriptions render the analysis of alternatives more challenging[200], but under the essential use concept, the use description would have to be explicit about the use description in order to show whether or not it is essential for society.

The ability of clearer use descriptions to reduce the administrative costs of derogations is exemplified by the cadmium case study explored under Task 3 of this project, which shows that the derogation of cadmium for 'safety reasons' (without further description of uses this could justify) resulted in significant debate and effort from ECHA to clarify the meaning of the derogation. In 2011, the European Commission requested ECHA to investigate the use, then in 2012, ECHA documented that Member States expressed concerns that the derogation was difficult (if not impossible) to enforce[201], and in 2015, ECHA developed further clarification on the uses to which

[200] European Commission, (2018). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Commission General Report on the Operation of Reach and review of certain elements. COM(2018) 116 final. 5th March 2018.
[201] European Chemicals Agency, ECHA (2012). The use of Cadmium and its Compounds in Articles Coloured for Safety Reasons (Derogation in Paragraph 3 Of Entry 23 Of Annex XVII). 9th November 2012.

the derogation could be applied[202]. The administrative costs (from time and resources) involved in these activities could have been avoided if the essential use concept had been applied so that it was clear from the start of the derogation that uses must be *necessary for safety* in line with the criteria in Part B of this report, not only for *safety reasons*, avoiding lengthy discussions and the need for clarifications.

Some stakeholder feedback raised concerns that administrative costs could be increased. For example, industry suggested that immediate costs to authorities in implementing the concept would be severe if an overwhelming number of applications for derogations and authorisations are submitted in response to the implementation of the essential use concept, as authorities would have a large number of applications to evaluate. This impact may occur due to GRA rather than the essential use concept (as GRA would be a driver of restrictions while the essential use concept would be used for derogations); therefore this is not considered an impact relevant to this project (but the wider reform of authorisation and restriction, addressed under a separate contract (VVA, Unpublished)).

There is a risk that the proportion of cases where essentiality is unclear may be high, which could lead to a large number of appeals or difficult and lengthy decision-making for authorities (e.g. the Commission). The scale of this risk is uncertain, given that only two REACH substances were investigated in the case studies under this project. Both cases investigated would have likely qualified as necessary for health with no available alternatives, therefore been identified as essential for society more easily than identifying that socio-economic benefits outweigh risks.

Any impact on administrative costs could be substantial given that, for many substances, a very high number of applications for authorisations have been received (e.g. 122 applications for authorisations of hexavalent chromium compounds)[203]. The magnitude of any impact is therefore dependent on how changes to restriction and authorisation would influence the number of applications for authorisations.

If the essential use concept simplifies the administrative costs required to evaluate authorisations and derogation requests from restrictions, this could have substantial benefits to administrative costs by making the process more efficient. Although there is high uncertainty regarding this impact, limited evidence from previous restrictions and authorisations indicates that this impact could occur. If, on the other hand, the concept does not simplify the process, it could exacerbate the existing problem of high administrative costs.

VVA (*Unpublished*) has made an attempt to estimate such possible cost savings to authorities which could occur due to the essential use concept. However, the VVA study is not finalised at the time of writing and precise figures cannot be quoted.

[202] European Chemicals Agency, ECHA questions and answers, (2015). Which types of articles coloured with mixtures containing cadmium can be regarded as using cadmium for safety reasons (derogation in paragraph 3 of entry 23 of Annex XVII to REACH)? Retrieved 2022-11-23 at: https://echa.europa.eu/da/support/qas

[203] European Chemicals Agency, ECHA (2021). Socio-economic impacts of REACH authorisations. ECHA-20-R-14-EN. April 2021.

In section 10.5.5, the possibilities of either establishing a new committee or reorganising the activities of the Member State Committee, to assess criticality for the functioning of society and necessity for health or safety were investigated. The costliest of these options would likely be the establishment of a new committee, although, to some degree and depending on policy option and sub-option, these costs would be counteracted by shifting resources from SEAC and RAC (as at least part of the responsibility for assessing applications for authorisations would be shifted to the new committee).

The possible costs to set-up a new committee for assessing the criticality for the functioning of society and the necessity for health/safety were investigated by ECHA following request by the project team. Costs based on the formation and operation of current ECHA committees (RAC and SEAC) are considered as a proxy for potential costs of a new committee:

- Set-up costs of RAC €17.4 million (€10 million related to restriction and authorisation); set-up costs of SEAC €9.7 million.
- Annual running costs of RAC €8.4 million (€4.7 million related to restriction and authorisation); annual running costs of SEAC €4.5 million. For each committee, direct costs were approximated at €0.7 million and €0.6 million respectively, with the remaining costs reflecting committee and ECHA staff time.

ECHA noted that the workload of a possible new committee for the essential use concept would likely have costs similar to SEAC and RAC (restriction and authorisation only) and therefore costs would be expected to be approximately **€9.7 – 10 million** (short term set up costs) and **€4.5 – 4.7 million** (long term annual costs).

These cost estimates include time of committee members, their advisers, the co-opted members and stakeholder representatives, as well as chairs and ECHA staff. Direct costs of running the committees (travel, accommodation and rapporteurship costs) are also included. Some miscellaneous (e.g. event management, IT) costs are estimated so that the total costs of the committees can be estimated. would consist of time developing the rules of procedure and guidance.

Likelihood: The essential use concept may reduce administrative burden to authorities, however the evidence described above is insufficient to conclude on how probable this would be. Costs would certainly be borne through (re-)organising a (new or existing) committee to assess criticality for the functioning of society and necessity for health/safety.

11.6.2 Administrative burden to industry

Impact categories (BRT Tool #18): Administrative burden.

Type of impact: Uncertain

Description: Short-term adjustment costs would be expected following implementation of the essential use concept due to changes in requirements for what information needs to be gathered, analysed and presented by industry to apply for authorisations and request derogations from restrictions (note, this would be a new process under certain policy options). These adjustment costs would be expected to decrease over time. There could be long term impacts to administrative burden due to changes in the level of difficulty in gathering and presenting information on essentiality in comparison to information on risk and benefits through SEA or adequate control which may currently be used to justify authorisations. Administrative burden would also arise from compliance with conditions from essential uses (in Part B of this report).

This impact is particularly sensitive to the policy options for the reform of authorisation and restriction given that stakeholders have different responsibilities in each option. For example, some policy options would grant industry the opportunity to request derogations from restrictions,

introducing new administrative burden. This could amplify any impact of the essential use concept on administrative burden. On the other hand, where authorisation is removed and there are no opportunities for industry to request derogations from restriction, this impact would be reduced (and only include burden from contributions through restriction consultations). Impacts due to changing roles of responsibility fall under the scope of the VVA study on the reform of authorisation and restriction and are not considered impacts of the essential use concept.

Significance: Under the baseline, administrative burden on industry is high due to applications for and compliance with authorisations and compliance with restrictions.[204] The average annual cost to companies preparing applications for authorisation was estimated by ECHA (2021) to be €7 – 9 million.[205] Industry has no *formal role* in decisions on derogations from restrictions, although they are generally involved in the consultations during the restriction process (providing evidence in response to the restriction report and SEAC's draft opinion). The administrative burden associated with consultation is uncertain.

Impacts are described below in terms of proportion of authorisation applications; difficulty in gathering and providing information; and complying with conditions for essential uses.

Proportion of authorisation applications – The essential use concept would introduce clear criteria to guide which types of uses could be derogated/ authorised, which could deter applications for authorisations, thereby, reducing the proportion of applications for authorisations. This is based on the assumption that the essential use concept could bring better predictability. That is, clear criteria may help companies know if their use is essential for society without conducting a thorough assessment, thereby reducing wasted administrative burden on non-essential uses. NGOs were supportive that the essential use concept could save time and effort.

This impact is highly uncertain as it is unclear how industry would respond to the essential use concept, in terms of whether they would be discouraged or encouraged to apply for authorisations. For example, although applications for clearly non-essential uses will be discouraged, applications for uses which somewhat relate to the criteria (e.g. relate to health but are not necessary for health and safety) could potentially be encouraged. Some industry stakeholders provided feedback that they expect an overwhelming number of applications for uses to be submitted.

Difficulty in gathering and providing information - The essential use concept would influence the type of information and analysis required to justify and comply with an authorisation requirement.

Under the baseline:

- Authorisations granted via the SEA route rely on information on the "applied for use" and the "non-use" scenario, as well as socio-economic, human health and environmental impacts associated with both.
- Authorisations granted via the adequate control route rely on information on the risk and risk management measures related to a use.
- Derogations from restrictions are set by authorities, taking into account the evidence from industry provided in consultations. This information usually includes evidence of socio-economic benefits, unavailability of alternatives and risks.

[204] European Commission, (2018). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the operation of REACH and review of certain elements. COM(2018) 116 final. 5th March 2022.
[205] European Chemicals Agency, ECHA (2021). Socio-economic impacts of REACH authorisations — A meta-analysis of the state of play of applications for authorisation. ECHA-20-R-14-EN. January 2021.

Under the essential use concept:

- Information on criticality for the functioning of society / necessity for health/safety and lack of available alternatives for a use would be needed to justify essentiality for society.
- Justifying the authorisation or derogation from restriction would require evidence that the use, emissions, and exposure are minimised as far as possible.

Some parallels exist between the baseline and the essential use concept, for example, both require evidence on the use and the availability of alternatives. Analysis of alternatives under the essential use concept would follow the same (or at least similar) process as the baseline, therefore no difference is expected here.

In terms of information on use, the 2018 REACH review identified that information on use is often lacking from authorisation applications, hindering the ECHA Committees' opinion making. Although industry have commented in consultation that generating information on use for the essential use concept would be challenging, it is notable that information on use should already be gathered today under the baseline for authorisation (substance function, product, technical requirements, industry sector). The essential use concept would require this information to be contextualised in the frame of essentiality for society, which may be more challenging to some degree.

Both the baseline and essential use concept require evidence on exposure/emissions to derive a risk, however, in different contexts. The baseline requires evidence to derive risk to demonstrate that benefits outweigh risk or risk is adequately controlled, while the essential use concept would require evidence on measures to demonstrate that the essential use and associated emissions and exposure have been minimised. It is difficult to assess whether information gathering would be more or less challenging for the essential use concept, given that no general definition for minimised use, emissions, and exposure was identified and that this is likely to vary on a substance-by-substance basis. The case-by-case approach is also applied currently in authorisations.

The essential use concept is likely to require less socio-economic data and analysis, however, this is difficult to assess as the weight of evidence required to prove that a use is critical for the functioning of society / necessary for health/safety may be high in some cases. At least for some uses, the information required should be significantly simpler, as demonstrated by the strontium chromate case study under Task 3 of this project. Significant variability between cases would be expected.

The essential use concept could have decreased the administrative burden required with gathering and analysing socio-economic data to justify the authorisation of strontium chromate (Cr(VI)) for use in the application of primers and specialty coatings in the construction of aerospace and aeronautical parts. This use is important for the safe operation of aircraft and spacecraft, therefore quite clearly necessary for safety. Reaching this conclusion is expected to be simpler than reaching the conclusion that socio-economic benefits outweigh risk as it does not require the collection and weighing of economic and risk data, only a sufficient use description which conveys the necessity for safety. The essential use concept would not lower the burden in terms of assessing the availability of alternatives, as this is required both under the baseline and essential use concept.

In comparison to the adequate control route for authorisation under the baseline, the essential use concept would likely result in increased administrative burden in terms of providing and analysing information. Both require information on risks and risk management measures, while the essential use concept also requires evidence on the essentiality of the use for society (including the demonstration of the lack of alternatives which is not part of the adequate control route criteria).

Administrative burden to comply with essential use conditions – Under the baseline, conditions for authorisations and derogations usually exist, although derogations may be unconditional. However,

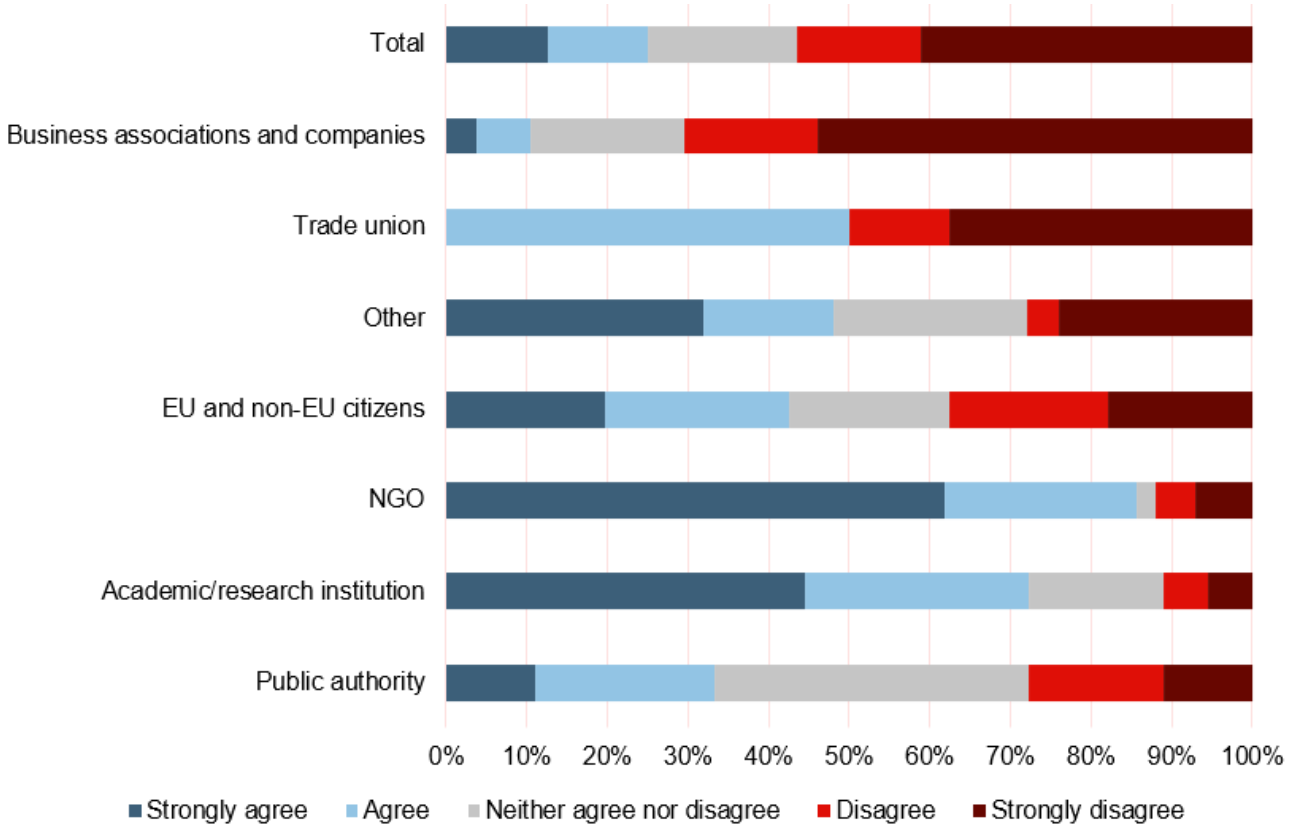
according to the essential use criteria proposed in Part B of this report, all derogated/authorised uses would have to: 1) require industry to minimise the use, exposure and emissions; 2) be time-limited; and 3) be contingent upon industry demonstrating appropriate effort to substitute.

These conditions would add to administrative burden, for example, time and resources required to demonstrate through monitoring and reporting that appropriate effort is being made to substitute the use. No quantified estimates for costs related to demonstrating progress towards substitution were identified.

Stakeholder views

Stakeholders show diverging views on whether the essential use concept would lead to economic benefits for industry. Industry representatives predicted that impacts would be negative, while other types of stakeholders generally showed more support (than disagreement) that the essential use concept would lead to economic benefits for industry (Figure 11.3). The disagreement from industry is of concern given that they will be impacted by the potential changes in administrative costs.

Figure 11.3 Stakeholder responses to the public consultation on the revision of REACH question "do you agree that applying an essential use concept specifically under REACH could lead to economic benefits to industry?



Industry expressed concern during consultation activities that the essential use concept would increase administrative burden because of the large number of substances impacted (the most harmful chemicals) and the large number of uses for each substance. However, the number of substances subject to the essential use concept depends on the policy options for the reform of authorisation and restriction, therefore this is not considered an impact of the essential use concept (rather an impact of the extension of GRA). If the essential use concept were not in place, administrative burden would still be required for the baseline requirements for authorisation and restriction.

Although the majority of industry views were negative, one industry association responded to the survey suggesting that the essential use concept could decrease burden provided that the information requirements are reasonable and practical. Another suggested that the concept could encourage better understanding of supply chains by different actors (relating to the administrative burden of gathering data along the supply chain but framed as a benefit).

Likelihood: The essential use concept could have significant impacts on administrative burden to industry given that current authorisation costs are high, and the impact of any change in administrative burden per application will be amplified if a large number of authorisation applications are expected (which would seem likely if GRA were extended).

The evidence described is not clearly indicative of whether the essential use concept would increase or decrease the administrative burden to industry. It is not clear whether the essential use concept would result in increased or decreased applications for authorisations (although it is intended to decrease applications and simplify the decision-making process). Furthermore, while the reduced information and analysis for SEA may reduce burden, the extent to which the efforts needed to prove essentiality for society could counterbalance this saving is uncertain. The difference in burden is likely to vary on a case-by-case basis and in some cases, the administrative burden of demonstrating that conditions for essential uses are met may also be high.

11.6.3 Impacts on profits and jobs for chemical manufacturers

Impact categories (BRT Tool #18): Conduct of business; functioning of the internal market and competition; employment.

Type of impact: Uncertain

Description: The essential use concept is expected to reduce the proportion of uses of the most harmful chemicals derogated from restrictions and authorised (see assumptions set out in section 6.3). This would reduce the level of demand from users of the controlled substances and increase the demand for their alternatives. This section describes the economic impacts that this may cause to chemical manufacturers, suppliers, and users.

For essential uses: Essential uses could be derogated/authorised both under the baseline and under the essential use concept (see assumptions in section 11.3). Therefore, impacts from the essential use concept on profits and jobs related to the manufacturing, supply, and use of the most harmful chemicals for essential uses are expected to be similar to the baseline. However, for substances with both essential and non-essential uses (for society), the loss of demand from downstream users for non-essential uses could negatively impact profits and jobs for chemical manufacturers. For example, if the loss of profit from non-essential uses is high, production of the substance could face economic challenges.

Loss of demand from downstream users for substances affected by the essential use concept will vary on a case-by-case basis, depending on the number of essential uses in comparison to the number of non-essential uses, as well as the volume of the substance required for different uses. For example, there may be cases where most uses of a substance are non-essential for society and the essential use (or uses) only require(s) a very low volume of the substance. In some cases, the volume of chemical required only for the essential use(s) may be too low for production to be economically viable (e.g. production plants may have high operating costs which might not be affordable to manufacturers if profits are reduced due to a reduction in sales). In severe cases where costs cannot be absorbed through the supply chain (e.g. due to high competition with non-EU manufacturers), this could result in loss of EU manufacturing of substances for essential uses. Cessation of manufacturing and supply of substances for essential uses would result in economic losses in terms of jobs and productivity.

For non-essential uses: The essential use concept would intentionally result in the cessation of production, supply, and use of the most harmful chemicals for non-essential uses. Therefore,

industry would incur economic costs in terms of job losses and profits as industrial activity would be reduced. For uses of substances which are not essential for society because suitable alternatives are available, any loss of profits from production of most harmful chemicals should be coupled with a shift of production and jobs to safer alternatives, rather than an absolute loss of profits; these may or may not be within the EU. Even if a use is not critical for the functioning of society or necessary for health and safety, it is likely that research and development in alternatives (and up-scaling production, if alternatives are available) would increase, depending on societal demand. With an increased production of alternatives, their developers and manufacturers are expected to benefit from a larger market, with related profit gains and creation of jobs. This would counter-balance some of the negative impacts, although it is uncertain and difficult to assess to what extent. The increased demand for alternative substances and technologies could also have a positive impact on research and innovation.

Significance:

For essential uses: The significance of impacts from reduced demand for volume of substances affected by the essential use concept is uncertain. For each substance, the number of essential uses and non-essential uses will vary substantially (as well as the volume required for each type). Furthermore, the threshold at which production becomes no longer economically viable will vary between production plants. There may be costs to industry in scaling down production, e.g. by using different apparatus or synthetic routes. No evidence from past instances of restrictions resulting in problems with economic viability of production for derogated uses was identified.

For non-essential uses: The expected costs to industry from derogations from restrictions / authorisations **not** being made are difficult to estimate. ECHA (2020) estimated that the annual socio-economic benefits from authorising certain uses of carcinogens and reprotoxic substances could be monetised at €8.7 billion, including benefits to industry from continued use (business maintenance and job security) as well as continuous availability of specific products and services to consumers. However, ECHA noted that due to limitations the benefits from continued use had not been conclusively established. The essential use concept could reduce these benefits to some (unknown) degree.

For derogation to restrictions, previous analyses, e.g. ECHA (2021)[206], focus on the costs and benefits of restrictions rather than derogations from restrictions. It is therefore difficult to assess the scale of the impact from the essential use concept.

In terms of shifting jobs from the production, supply and use of the most harmful chemicals to safer alternatives, this would likely have an overall neutral impact in terms of number of jobs and profits. However, it would reflect a positive step towards a more sustainable economy (e.g. reducing the use of the most harmful chemicals could contribute towards the EU's zero pollution ambition). Several economic benefits are associated with improvements in sustainability, for example, consumers are more likely to purchase sustainable products.[207]

Likelihood:

- It is unclear how likely it is for negative impacts on industry profits and jobs related to substances produced for essential uses.
- There is a high likelihood that the essential use concept would cause disruption to the conduct of business in the short term as production of substances for non-essential uses would cease. Where alternatives are technically and economically feasible already, negative economic impacts will be counteracted by benefits to manufacturers and users of alternatives (if within the EU). Where alternatives are not available and

[206]European Chemicals Agency, ECHA (2021). Costs and benefits of REACH restrictions proposed between 2016-2020. ECHA-21-R-02-EN.
[207] Deloitte, (2022). How consumers are embracing sustainability. Retrieved 2022-11-22 at: https://www2.deloitte.com/uk/en/pages/consumer-business/articles/sustainable-consumer.html

the use is not critical for the functioning of society or necessary for health and safety, the short-term economic costs might be significant, although restrictions typically include transition times before they take effect, which could reduce the costs by allowing manufacturers and users to prepare for withdrawal of the use.

11.6.4 Substitution costs to industry

Impact categories (BRT Tool #18): Conduct of business; functioning of the internal market and competition; employment.

Type of impact: Negative

Description: The essential use concept is intended to incentivise the substitution of essential uses by requiring substitution plans and time limits for derogations (in comparison to the baseline which only includes these for some derogations and authorisations). Substitution requires time and effort from industry to research, develop, and test alternatives. These costs could be partly offset by wider economic benefits in terms of the creation of new jobs.

Alternatives may be more or less expensive than the most harmful chemicals which they are substituting. If alternatives are more expensive, their users will face higher costs, which would translate either to reduced profits or to increased prices for customers (in case it is possible to pass on the costs down the supply chain). If alternatives with lower performance are considered acceptable (which will vary on a case-by-case basis depending on performance requirements), this could incur greater costs in the long term. For example, less durable or effective alternatives may be required in greater quantities and may result in the need to replace products more frequently.

Significance: ECHA (2020) investigated costs associated with substitution in the context of REACH restriction and authorisation[208] and found that substitution may take a number of years to achieve (44% of survey respondents (companies) estimated that substitution could be achieved in less than 3 years, while 20% estimated 4 – 6 years, and 36% estimated more than 7 years). Over this time, the effort translates to financial costs. For substitution in less than 3 years, annual costs were mostly predicted between the range of €50 000 to €1 million (54% of respondents), while 19% estimated no costs. For one-off costs for substitution taking more than 7 years, 27% of respondents estimated no costs, while 22% estimated that substitution costs may exceed €50 million in total. Costs over €50 million have been experienced for substances subject to REACH authorisations, for example, trichloroethylene and chromium trioxide. In terms of annual costs for substitution, 38% of respondents estimated costs over €10 million, while 17% estimated costs of €1 million to 10 million, 19% estimated costs of €100 000 to €1 million, and the remaining respondents estimated lower costs.

Given the variance between costs for each substitution case, it is difficult to predict the significance of the impact of the essential use concept on substitution costs, however, they may be substantial.

Likelihood: There is a high likelihood the essential use concept would increase substitution costs to industry.

11.6.5 Costs to industry to minimise the use, emissions, and exposure associated with most harmful chemicals

Impact categories (BRT Tool #18): Conduct of business; functioning of the internal market and competition; employment.

Type of impact: Negative

[208] European Chemicals Agency, ECHA (2020). Impacts of REACH restriction and authorisation on substitution in the EU. ECHA-20-R-09-EN. July 2020.

Description: In comparison to the baseline, the essential use concept (as proposed in Part B) would require stricter conditions for essential uses which are derogated or authorised. The baseline includes these on a case-by-case basis for authorised uses (e.g. risk management measures and operational conditions for authorised uses) but only rarely for uses derogated from restrictions. To comply with the conditions under the essential use concept, industry must demonstrate that it takes measures (e.g. risk management measures) to minimise the use and any associated emissions of and exposure to the controlled substance at all lifecycle stages, including waste and recycling. Consideration of all lifecycle stages goes beyond typical requirements for authorisations under the baseline. Should the risk management measures described in the derogation request not prove that the use/exposure/emissions have been minimised as far as possible, the decision-maker could impose conditions to introduce additional risk management measures.

Significance: It is difficult to estimate the significance of the costs associated with additional risk management measures. Some risk management measures are simple and low/no cost (e.g. organisational measures), while others may include major process changes, enhanced containment, ventilation. Costs will be specific to individual substances and uses. For example, a study on the Carcinogens and Mutagens (and since 2022 Reprotoxic Substances) Directive estimated that costs of risk management measures implemented by companies range from €300 to €1 700 000 of capital expenditure.[209]

Likelihood: There is a high likelihood that if the essential use concept is implemented in line with the conclusions in Part B of this report, industry costs to minimise the use, emissions, and exposure associated with the most harmful chemicals will increase.

11.6.6 Impacts along the supply chain

Impact categories (BRT Tool #18): Employment; consumers and households.

Type of impact: Negative

Description: Economic impacts to manufacturers and suppliers may result in secondary impacts to actors along the supply chain. The previous sections highlight that the essential use concept could result in additional economic costs to industry due to increased substitution efforts, loss of demand for substances, and increased efforts to ensure minimisation of uses, emissions and exposure associated with the most harmful chemicals. It is unclear whether the concept would reduce or increase the economic costs associated with administrative burden (as the evidence is insufficient to determine whether information required to assess essentiality would be easier to gather and analyse in comparison to the information required to conduct SEA under the baseline).

If the overall economic impacts to manufacturers and suppliers are negative (e.g. administrative burden is not decreased, or increases), these may either be absorbed by reducing profit margins or through increasing prices along the supply chain. Given that essential uses are expected to have high societal importance, downstream users and consumers may be expected to be willing to pay more for associated products and services, allowing costs to be absorbed through the supply chain. However, EU manufacturers may suffer from high competition with manufacturers outside the EU. In response to previous REACH-related costs, most EU companies have reduced profit margins (e.g. to absorb registration costs[210]). The essential use concept may similarly result in pressure on prices from competitive markets, potentially damaging the revenue of some companies.

[209] FoBiG *et al.,* (2018). Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC. VC/2017/0011.
[210] Wood *et al.,* (2021). Study on the impacts of the 2018 REACH registration deadline.

For uses which are not critical for the functioning of society or necessary for health and safety and there are no alternatives (hence, uses that are not essential for society), the supply chain would likely be disrupted because the lack of available alternatives indicates that a restriction of a given substance without derogation / authorisation would mean that the final product / process could not be produced or would be produced with a lower performing alternative. This would result in costs to actors along the supply chain.

Significance: If the essential use concept results in greater overall costs to industry, these could in some cases be absorbed in the supply chain (where competition from non-EU manufacturers does not prevent this), resulting in higher prices for downstream users and consumers. The nature and scale of this impact would likely vary on a case-by-case basis. In extreme cases, higher prices along the supply chain could lead to affordability issues for consumers and lead to loss in consumer surplus (i.e., the cost of producing the chemical may rise above what people are willing to pay and therefore cannot be absorbed by the supply chain). This would result in the costs being born by manufacturers who would suffer economically in terms of reduced profit or job losses.

Likelihood: High likelihood that costs related to essential uses will reduce profit margins of producers, and in cases of severe costs, the costs may increase through the supply chain. The potential for absorbing costs through the supply chain may be limited by the competitiveness of chemical markets, as was noted with the 2018 REACH registration.

11.6.7 Impacts on global competitiveness and innovation

Impact categories (BRT Tool #18): Conduct of business; functioning of the internal market and competition; technological development / digital economy; Innovation (productivity and resource efficiency); research (academic and industrial).

Type of impact: Uncertain

Description: The essential use concept is expected to change the production and use patterns of the most harmful chemicals and encourage the development, uptake, and use of safer alternatives. This could have repercussions on the global competitiveness of the EU chemical industry.

Negative impacts on global competitiveness may be expected in the short term due to disadvantages to EU companies. The costs described in the above sections (impacts on profits, jobs, substitution costs etc.) would affect companies manufacturing products in the EU but not in third countries (although costs in each non-EU country will depend on how the relevant substances are controlled in each third country). EU manufacturers would therefore be disadvantaged in terms of sales outside of the EU. Under the baseline, this problem would also likely affect sales within the EU because of the lack of provisions in REACH to ensure compliance of imports, although policy options under the revision of REACH are being developed to address this problem.

Industry representatives and companies generally agree that authorisation limits competitiveness and innovation as investors may be discouraged from investment in the EU if it cannot be guaranteed that the company will be able to use the substance in the future.[211] The essential use concept could exacerbate this negative impact in comparison to the baseline as essential use decisions are to be time-limited (see Part B of this report).

Time-limited authorisations and complete bans (which could be encouraged by the essential use concept) are thought to encourage the relocation of production facilities outside of the EU. This is unlikely to be feasible for SMEs, putting them at an economic disadvantage.[212]

[211] European Commission (2015). Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs. Ares(2015)5889146 - 16/12/2015

[212] European Commission (2015). Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs. Ares(2015)5889146 - 16/12/2015.

On the other hand, positive impacts on competitiveness (in the EU and globally) may occur from increased substitution with safer alternatives (based on assumptions set out in section 11.3).

The essential use concept is intended to incentivise R&D efforts towards safer alternatives, which would help the EU maintain its position as a frontrunner in the transition to safe and sustainable chemicals, improving global competitiveness in this aspect. Furthermore, EU legislation has often set an example for legislation in other parts of the world, and hence changes such as the essential use concept could have a spill-over effect if the essential use concept were adopted in other jurisdictions.

Furthermore, the environmental impacts on the circular economy, as described in section 11.4, could have positive economic consequences as they could result in increased competitiveness of the EU recycling industry. This would be aligned with EU ambition set out in the CSS to ensure that "Recycled in the EU" becomes a benchmark worldwide.

Significance: Despite potential negative impacts from reduced use of the most harmful chemicals, the substitution of the most harmful chemicals with safer alternatives is a critical process to support the CSS vision of the EU industry as a globally competitive player in the production and use of safe and sustainable chemicals. The CSS recognises innovating for safe and sustainable chemicals as an opportunity for the EU chemical industry to regain competitiveness, given global trends.

Overall, the impacts on competitiveness from the essential use concept are expected to be less than those caused by the underpinning restrictions and additions to Annex XIV which are the main drivers.

Likelihood: High likelihood that the essential use concept would negatively impact global competitiveness based on the reduction of non-essential uses of the most harmful chemicals which will continue to be used outside of the EU. On the other hand, there is a high likelihood the essential use concept would encourage substitution with safer alternatives, therefore improving the EU's position as a global frontrunner in the production of safe and sustainable chemicals and products. It is difficult to weigh these impacts against each other.

11.7 Summary of impacts

11.7.1 Environmental impacts

Positive impacts (not quantified and uncertain) would be expected from increased environmental protection against the most harmful chemicals. The essential use concept would result in reduced use of the most harmful chemicals in comparison with the current processes for granting authorisations and derogations from restrictions which would continue if the essential use concept were not introduced (assumptions set out in section 11.3). Further environmental benefits would be expected through the transition to a circular economy, as reducing the presence of the most harmful chemicals in materials would increase the recyclability of materials and products, promoting sustainable production and consumption. The decrease in use of the most harmful chemicals would be expected to be coupled with an increase in safer alternatives, which could bring wider sustainability benefits if the essential use concept is implemented in a way that introduces a stronger incentive (or requirement) to develop sustainable alternatives.

11.7.2 Social impacts

Positive impacts (not quantified and uncertain) would be expected from increased human health protection against the most harmful chemicals, due to the reduced use of the most harmful chemicals as noted above in the context of environmental impacts. This could bring benefits through reduced incidence of health outcomes such as cancer, cardiovascular disease, endometriosis, male infertility, diabetes and others. Further positive social impacts could arise from

improved consumer satisfaction due to increased safety and sustainability of products on the EU market.

Potential negative impacts could arise if the loss of profits from non-essential uses of a chemical results in economic challenges to manufacturers, and if these result in entire loss of the chemical so that essential uses are lost from society. This is considered unlikely because of the possible responses (other manufacturers (in the EU or exporting third countries) could supply the substance or costs could be absorbed along the supply chain). Minor negative impacts could arise from loss of non-essential uses to society, as this may result in reduced consumer choice.

11.7.3 Economic impacts

Economic impacts of introducing the essential use concept are highly uncertain because it is unclear whether information required to demonstrate essentiality for society would be more or less difficult to gather and analyse in comparison to information requirements to demonstrate that socio-economic benefits outweigh risks of continued use and there are no suitable alternatives or that uses are adequately controlled. This would likely vary on a case-by-case basis. It is also difficult to predict how applicants for authorisations / derogations from restrictions would respond to the essential use concept. It is likely that the information requirements would be easier to fulfil, decisions would be easier to make and applicants would be deterred from applying for authorisations or derogations from restrictions for uses likely to be deemed non-essential for society.

Adjustment costs would incur to both industry and authorities. Depending on how the essential use concept is introduced, this could result in costs to authorities to establish a new committee, or reorganise an existing committee.

Costs to industry would be expected from loss of production and associated profits from non-essential uses of the most harmful chemicals. These costs would be counterbalanced where alternatives are available as developers and manufacturers of safer alternatives would benefit.

Substitution costs and the requirement to minimise essential uses and their associated emissions and exposure would likely lead to costs to industry, which may lead to decreased profit margins and/or be (partially) absorbed along the supply chain. There is a possibility that in some cases, decreased profits and increased costs could lead to feasibility issues with production, resulting in cessation of manufacturing and disruption of industrial activity. As described in the above section on social impacts, this is considered unlikely.

EU companies would be placed at a competitive disadvantage in comparison to non-EU countries who may still use the most harmful chemicals in non-essential uses, therefore non-EU companies would not face the substitution costs that would limit EU companies. On the other hand, the EU would gain competitiveness in the production of safer and more sustainable alternatives and remain a prominent leader in terms of chemical regulations.

12 How do the options compare?

12.1 Overview

This chapter provides a brief comparison of sub-options for the essential use concept. Impacts from the various sub-options for the essential use concept can only materialise through (or in combination with) the implementation of provision for authorisation and restriction, and therefore, **will depend on the preferred option chosen for the reform of authorisation and restriction.** This is not known at the time of writing.

Based on the description of sub-options and assumptions set out in section 11.3, a narrative comparison of options is provided below, following a tabular comparison between the impacts of each sub-option.

12.2 Descriptive comparison of options

Identifiability: Sub-options A and B would result in the same changes to REACH processes and only differ in terms of how they would be implemented, i.e., sub-option A would be non-binding while sub-option B would be binding. Sub-options A and B would therefore not be likely to differ materially in terms of the proposed measures and their significant impacts.

Legal feasibility: Based on the analysis from the project team, all sub-options for the essential use concept appear legally feasible, although there is less certainty for sub-option B given that Article 291 of the TFEU empowers the Commission to introduce implementing acts where uniform conditions are needed. In the end, it is the Commission's responsibility to conclude on the legal feasibility of sub-options.

Predictability: The application of the essential use concept is assumed to be most predictable for the Commission and industry under sub-option D because the concept would be the only tool used to grant derogations from restrictions and authorisations. Sub-options A and B would be less predictable as the essential use concept would be an optional consideration in addition to the existing criteria for derogations and authorisations, therefore also making the existing criteria less predictable. Sub-option C would bring greater predictability for restrictions but less predictability for authorisations.

Systematic application of the essential use concept: Linked to the previous point on predictability, sub-options C and D allow for a systematic use of the essential use concept as it would be legally binding to justify derogations or authorisations based on essentiality criteria. In sub-option D, this would be systematic for all relevant REACH processes (derogations from restrictions and authorisations). In sub-option C, this would be systematic for derogations from restriction but not for authorisation where the essential use concept would only be an optional consideration within the SEA route. In sub-options A and B, criteria for essential uses would only be considered *within* the socio-economic analysis, *if deemed relevant* by interested parties (including the Commission) and in decisions on derogations from restrictions.

Level of ambition: Sub-options A, B, C, and D vary in level of ambition for phasing out the most harmful chemicals. To rank the sub-options in order of effectiveness in phasing out the most harmful chemicals:

- Sub-option D is the most ambitious (as only essential uses could be allowed, with the essential use concept replacing all current tools for justifying and assessing authorisations or derogations from restrictions).

- Sub-option C is the second most ambitious as the essential use concept would be used alongside the current mechanisms.
- Sub-options A and B are the least ambitious as application of the essential use concept would be optional and the extent to which it would apply is uncertain.

Environmental and human health impacts: Sub-option D would have the most positive impact on the environment and human health, followed by sub-option C and lastly A and B.

Economic impacts: Economic impacts overall are uncertain (e.g. in terms of change in number of applications for authorisation or requests for derogations from restrictions as a result of the essential use concept, as well as the difference in difficulty in obtaining and assessing information on essentiality in comparison to information on socio-economic benefits and risks), therefore it is difficult to compare between the sub-options. The following observations are made:

- Sub-options A, B, and C might incur increased costs in terms of preparing and assessing applications for authorisations and derogations from restriction as considerations of essentiality for society would be in addition to current considerations. Sub-option D would replace the current information requirements in authorisation and for proving derogation from restrictions by information to prove essentiality. There are high uncertainties regarding economic impacts and costs may differ between cases (and depend on the specific use and specific substance). On average, the costs of gathering and assessing information to prove essentiality for society may roughly remain the same as the costs for proving the current legal criteria in authorisation (socio-economic considerations and adequate control).
- On the other hand, sub-option D would result in higher costs to industry in terms of substitution costs and costs to minimise essential uses and their associated emissions and exposure.
- Differences in predictability would influence economic impacts, as greater predictability would dissuade applications for authorisations and derogations from restriction which are likely to be rejected (due to clear non-essentiality for society). This would benefit industry (through saved resources in avoided applications likely to be rejected) and authorities (through reduced applications to assess and decisions to make). In line with the above analysis of predictability, sub-option D could increase these benefits, while A, B, and C have some limitations in predictability. Importantly, this depends on how industry interprets the term “essential”, e.g. if they respond to the concept by submitting requests for derogations and applications for authorisations for non-essential uses which are only somewhat relevant to health/safety or the functioning of society.
- Sub-option D would most likely (compared to the baseline and sub-options A, B and C) reduce the competitiveness of EU manufacturers and suppliers of the most harmful chemicals in comparison to non-EU manufacturers and suppliers. At the same time, sub-option D would most likely increase the competitiveness of companies manufacturing and supplying safer and sustainable alternatives (compared to the baseline and sub-options A, B and C). In addition, it could give EU manufacturers and suppliers of alternatives an increased competitive advantage if the essential use concept were adopted in other jurisdictions (i.e. spill-over effect, as has been the case with other REACH processes).

Coherence with EU policy objectives: The Chemicals Strategy for Sustainability requires that criteria ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. Sub-option D is more coherent with this objective as other sub-options allow for uses to be authorised based on the adequate control route and/or based on socio-economic grounds.

12.3 Comparison of impacts across sub-options

The table below shows a qualitative analysis of the predicted impacts of each sub-option, based on the content of chapter 6. Predicted nature and scale of each type of impact is shown in yellow to facilitate identification of the most significant impacts (dark yellow). For each sub-option, the scale and magnitude are estimated, showing positive impacts (green) and negative impacts (orange). Unclear impacts are depicted in grey.

Table 12.1 Comparison of impacts across sub-options for the essential use concept in REACH (against the baseline, e.g. a '+' shows a positive impact of the sub-option against the baseline)

Impacts	Predicted nature of impact (as concluded in section 11)	Estimated likelihood (note high uncertainty)	Sub-option A and B (shown together as the impacts are not expected to differ substantially)	Sub-option C	Sub-option D
Environmental impacts					
Environmental health	Very positive	Very likely	+	++	+++
Transition to a circular economy / sustainable production and consumption	Positive	Very likely	+	++	+++
Avoidance of regrettable substitution	Neutral - positive	Unlikely - likely	- (guidance on AofA likely to be similar, pressure to substitute likely to be higher)	++	+++
Substitution with sustainable alternatives	Weakly positive	Likely	n/a	+	+
Social impacts					
Human health	Very positive	Very likely	+	++	+++
Loss of uses which could be necessary for health/safety in the future	Very negative	Unlikely	-	-	- -
Consumer choice	Weakly negative	Unknown / likely	-	- -	- - -
Consumer satisfaction	Weakly positive	Unknown / likely	+	+	+
Loss of essential uses	Very negative	Unknown / unlikely	-	- -	- - -
Economic impacts					
Administrative costs to authorities	Uncertain	Unknown	Intended to be +	Intended to be ++	Intended to be +++
Administrative burden to industry	Uncertain	Unknown	-- (any essentiality considerations would be in addition to current requirements)	-- (any essentiality considerations would be in addition to current requirements)	Intended to be +++ (dependent on reaction of industry to the concept)
Profits and jobs for chemical manufacturers	Uncertain	Unknown	Positive for alternative manufacturers, negative for most harmful chemical manufacturers	Positive for alternative manufacturers, negative for most harmful chemical manufacturers	Positive for alternative manufacturers, negative for most harmful chemical manufacturers
Substitution costs for industry	Negative	Very likely	-	- -	- - -
Costs to minimise essential uses,	Negative	Very likely	-	- -	- - -

Impacts	Predicted nature of impact (as concluded in section 11)	Estimated likelihood (note high uncertainty)	Sub-option A and B (shown together as the impacts are not expected to differ substantially)	Sub-option C	Sub-option D
emissions, and exposure					
Costs along the supply chain	Negative	Likely	-	- -	- - -
Global competitiveness and innovation	Uncertain	Likely	Positive for safe chemicals, negative for manufacturers, suppliers, and users of the most harmful chemicals	Positive for safe chemicals, negative for manufacturers, suppliers, and users of the most harmful chemicals	Positive for safe chemicals, negative for manufacturers, suppliers, and users of the most harmful chemicals

Table 12.1 indicates that sub-option D appears to score best in terms of the expected human health and environmental impacts, as well as legal feasibility, predictability and coherence. Sub-option D would likely have the most negative impacts in terms of substitution costs, costs to minimise essential uses, emissions and exposure and costs along the supply chain; sub-option D would likely have the most positive impacts in terms of administrative burden for both industry and public authorities. Impacts from sub-option D in terms of profits and jobs are uncertain, and therefore, it is difficult to conclude on the extent to which the positive and negative economic impacts balance out. The uncertainty regarding expected impacts (especially economic impacts), also described in section 11.3 and above, is an important consideration.

This conclusion on the sub-options does not prejudge the final decision by the Commission in the context of the revision of REACH, ongoing at the time of writing. For example, the Commission may choose to combine individual elements from each sub-option in order to devise a preferred option.

Appendix A
Legislation screening overview

This appendix is part of a study to support the European Commission in developing an 'Essential Use Concept' to be applied in EU chemicals policy. The table below provides a brief summary of outputs of the Task 1a on 'legislation screening'. This document presents key conclusions from the screening, highlighting the EU legislation that can help inform the essential use concept and where legislation could potentially be improved with the implementation of the essential use concept. The full output of the screening fed into the analysis carried out as part of the final report.

In Task 1 of this project, a rapid screening of relevant EU chemicals legislation was conducted, identified from the Commission Fitness Check of the most relevant chemicals legislation and Fitness Check of endocrine disruptors. The table below includes an overview of 44 pieces of legislation that were covered initial screening process under Task 1. Task 2 builds on the work of Task 1 by conducting a wider exhaustive information gathering exercise, including an in-depth analysis of relevant legislation prioritised in Task 1. Task 3 then develops and refines the concept of essential use and how this can be implemented in practice in several pieces of legislation (in addition to REACH) based on the outputs of Task 1 and 2. This full analysis can be found in the final report.

The table below includes a brief indication (YES/NO/PARTIALLY/UNCERTAIN) of:

- where/how the essential use concept[1], (or the different components thereof) is already considered under the legislation, and;
- if/how an essential use concept could potentially benefit the legislation.

Based on this screening, a preliminary indication has been provided on whether the legislation could be considered for prioritisation to be included in the analysis conducted in subsequent tasks. This has been further discussed with the Commission and further informed by the additional data gathered under Task 2, including direct consultation with the Commission staff involved with each piece of legislation. Ultimately the screening has been used to develop a list of pieces of legislation to be included in the Task 3 analysis (in addition to REACH) (see part B of the final report).

It should be noted that the screening has been completed based on a consideration of the essential use concept criteria, as presented in the Chemicals Strategy for Sustainability and initial discussions with the Commission (prior to the development of the essential use concept presented in this final report). The results presented in this appendix must therefore be viewed with caution, and where benefits of applying the essential use concept are set out, these should be read as potential benefits, dependent on the final criteria (that were developed later in the project) and how this is implemented in practice.

If a piece of legislation explicitly contains a concept of essential use the cell has been highlighted in green. If a piece of legislation contains the application of one of the elements of a concept of essential use, without the full application of the concept, then the cell has been highlighted in yellow. If the legislation does not contain this concept, the cell has been highlighted in orange.

If the criteria and implementation of the concept could benefit the legislation, two different colours have been used. Green indicates that the legislation could potentially benefit more from the definition and implementation of the concept than other legislation, highlighted in yellow. If the

[1] As presented in the Chemical Strategy for Sustainability, including consideration of i) use being necessary for health, safety or is critical for the functioning of society, and ii) if there are no alternatives that are acceptable from the standpoint of environment and health.

criteria and implementation of the concept would not be beneficial to a piece of legislation, the corresponding cell has been highlighted in orange. In nearly all cases, this is where the concept of essential use (or the components thereof) were seen as not relevant to the legislation, and where the specified criteria of assessing ‘essential use’ under generic risk assessment processed would not apply.

Table 1 Legislation screening overview

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
Regulation (EC) No 1907/2006	REACH (authorisation)	Partially – Absence of suitable alternatives is one of the criteria for granting authorisations (except where adequate control of risks can be demonstrated). Criticality for society/necessity for health and safety not an explicit criterion (but has played an implicit role in discussions4 on certain applications for authorisation and Court cases (e.g. T-837/16) The socio-economic assessment (SEA), if/when submitted, partially covers the relative importance of a use to society.	Yes – could allow a systematic (and relatively rapid) identification of where hazardous chemicals provide benefit in terms of health, safety or criticality for society in relation to authorisation applications. Furthermore, it could allow easy/early indication to manufacturers /downstream users if an application for authorisation is likely to be successful and provide saving of time and effort both for companies and public authorities (ECHA, COM, MS).	Yes
Regulation (EC) No 1907/2006	REACH (restriction, Article 68(1)	Partially - Assessment of alternatives is considered in the restriction process. The Alternative assessment includes: ● information on the risks to human health and the environment related to the manufacture or use of the alternatives, ● availability, including the time scale, ● technical and economic feasibility. ● The socio-economic impacts of the proposed restriction have to be assessed with reference to Annex XVI. The organisation preparing the restriction proposal (MS or ECHA) and the ECHA committees etc. implicitly and sometimes	Yes – It could potentially allow faster and more systematic decision making on restriction Proposals (Annex XV dossiers); clear criteria to assess if/what derogations from restriction is appropriate in the context of 'essential use' for society. However, it is uncertain if/how discussions on whether certain uses are essential will be less lengthy than the current discussions on derogations	Yes

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
		explicitly consider the importance of different uses to society in proposing derogations from restrictions. If restricting the substance(s) has high costs for society compared to the risk reduction, a derogation is usually proposed.		
Regulation (EC) No 1907/2006	REACH (restriction, Article 68(2)	Partially – Annex XV dossier is not required, restriction based on CMR properties. In practice, a (lighter touch) assessment of the implications of a restriction may be assessed e.g. the Commission has identified how to implement Article 68(2) restrictions for articles.	Yes – It could allow more systematic and consistent decision making on restriction Proposals (Annex XV dossiers). Clear criteria to assess if/what derogation from restriction is appropriate in the context of 'essential use' for society	Yes
Regulation (EU) No 528/2012	Biocidal products	Yes - Substances with specified hazard properties are automatically rejected unless essential to protect human health and non-approval of the substance can be proved to have a disproportionate impact on society. Member States may authorise non-approved active substance if it is essential for the protection of cultural heritage and there are no appropriate alternatives.	Yes – Essential use concept could provide criteria to evaluate if an active substance should be granted derogations, allow assessment of the level of 'disproportionate' impact' to society associated with restricting a chemical and aid in the comparison of alternatives.	Yes
Regulation No 1005/2009	Substances that deplete the ozone layer (known as the ODS Regulation)	Yes – Transposed from the Montreal Protocol (MP) which contains comprehensive definition and criteria for an essential use concept. For halons, an exemption is specified (Article 13) - halons may be placed on the market and used for critical uses set out in Annex VI.	NA/Uncertain - From the initial screening, it is not clear exactly how or to what extent the essential use concept is transposed from the MP in the ODS Regulation. Potential for a more stringent essential use concept to be applied in the ODS compared to the MP?	Yes

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
Directive 2009/48/EC	Toys	Partially - CMR substances can only be used in toy if specific conditions are fulfilled, including if there are no suitable alternative substances available.	Yes – could allow a systematic (and relatively rapid) identification of exemptions in cases where use of CMR substances provides a suitable benefit in terms of health, safety or criticality for society; and the potential to carry out a rapid comparison with alternatives to compare against consistent and systematic criteria.	Yes
Regulation (EC) No 1223/2009	Cosmetics (Generic assessment)	Partially - CMR substances can only be used in cosmetics if specific conditions are fulfilled, including if there are no suitable alternative substances available.	Yes – could allow a systematic (and relatively rapid) identification of exemptions in cases where use of CMR substances provides a suitable benefit in terms of health, safety or criticality for society; An essential use concept can provide a clear and consistent definition and procedure for determining if there are no 'suitable' alternatives.	Yes
Regulation (EC) No 1935/2004	Food Contact Material (FCM)	No	Yes – Noted that the legislation is undergoing revision. It is envisaged that the revised legislation will include the generic restriction of the most hazardous chemicals, with specified derogations, as applied under other EU legislation. The essential use concept offers the potential to strengthen the legislation with a consistent definition of 'essentiality'. Substances on the Union list are already subject to a risk assessment but are limited mainly to plastic FCM, with some exceptions (e.g. lead and cadmium in ceramics and glassware).	Yes

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
			The concept would be useful and could be applied for those substances that the most hazardous and for which a GRA is now foreseen.	
	Taxonomy, including Climate Change Delegated Act (EU) 2021/2139 (published in the OJ on 9 December: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R2139&qid=1639037016630)	Partial – it is noted that the legislative text (as written) explicitly refers to essential use of chemicals, there is no specified criterial for how this is defined.	Yes – the delegated act includes references to essential use. The delegated act specified generic criteria for do no significant harm (DNSH) to pollution prevention and control regarding use and presence of chemicals. The DNSH criteria ensures that substances that meet criteria for substances of very high concern (SVHC) are not manufactured, placed on the market or used, except where their use has been proven to be essential for the society (Appendix C: Generic criteria for DNSH to pollution prevention and control regarding use and presence of chemicals).	Yes
Directive 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment	Partially – The Directive prohibits the use of specific hazardous substances and substance groups (listed in Annex II). An amendment of the list of restricted substances is done periodically or triggered by a Member State proposal. A substance is included if the criteria in Art.6 are fulfilled, and the substance is in conflict with the objectives of the Directive. This includes consideration of whether a substance "could be replaced by substitutes or alternative technologies which have less negative impacts" i.e., alternatives assessment. As a derogation, to this restriction,	Partially – The exemption criteria are reviewed in the currently ongoing review of the RoHS Directive. This offers the potential to improve the efficiency of the process for updating the lists of substances in Annexes II, II and IV carried out under Art 6, using a defined criteria for essential use, applied to specific uses of the substance. Also offers the potential for closer alignment and better coherence with other EU legislation dealing with electronic waste (e.g., the End-of-Life Vehicles legislation), for example by applying the same derogation criteria.	Yes

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
		the applications can be listed as individual, time-limited exemptions in the Annexes III and IV (as set out on Art 5)– if specific criterial are met. This includes: One condition of the three bullet points must be fulfilled to be granted an exemption for up to 5 or 7 years. Technical applications with a valid exemption entry cannot be revoked without severe negative impacts for the society (e.g. lead in medical devices or lead in steel). The exemptions will be reviewed according to their expiry dates. The Directive therefore considers key aspects of essential use within the restrictions laud out. Since this does not refer explicitly to 'essentiality', the designation 'Partially is applied'.	It is noted that the Directive must ensure that changes made to Annexes II, II and IV "does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH)". The essential use concept could therefore ensure easier alignment between RoHS and REACH.	
Directive 2000/53/EC	End-of life vehicles	Partially – The Annex II (listing specific exemptions) shall be amended on a regular basis, in order to exempt certain materials and components of vehicles if the use of these substances is unavoidable. It is likely that these materials/components are exempt as their use is seen as 'essential' in some way. However, the process by which these materials and components were identified as essential is not provided.	Yes – Concept could be used within Annex II such that exceptions to the restriction of lead, mercury, cadmium and hexavalent chromium in vehicles could be more universally defined.	Yes

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
Regulation (EC) No 1107/2009	Plant Protection Products (PPP)	Partially - Art 4 specifies that an active substance must be approved in accordance with specified approval criteria (Annex II) Art 4(7) By way of derogation, Member States may authorise plant protection products containing active substances only when it is necessary to control that serious danger to plant health in their territory (Applied at EU level) Article 53 (Emergency situations in plant protection_ allows that "in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means" (Applied at MS level) In both cases there implicit reference to criteria of the essential use concept so a 'Partial' designation is made.	Yes - The essential use concept could [depending on final criteria and implementation] help apply relatively quick and consistent decision making when considering derogations under Art 4(7) It could also have the added benefit of improved efficiency for the legislation by deterring operators from submitting applications for derogation in the first place. Noted that for the emergency procedure (Art 53) there is a need to make decisions very quickly (but with a degree of flexibility built in). The essential use concept could allow quicker and more systematic comparison of alternatives when assessing candidates for substitution and could aid in approval of derogations.	Yes
Regulation (EU) 2019/1021	Persistent Organic Pollutants (POPs)	Partially - The concept of essentially is explicitly mentioned in relation to the considerations of derogations from restriction for specific POPs (Annex I). In the case of PFOS, the regulation states that	Partially - Concept could be useful in providing a clear and systematic approach to assessing the derogations/exemptions allowed under the Stockholm Convention and their societal implications.	Yes

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
		(a) the uses of PFOS will be phased out as soon as the use of safer alternatives is technically and economically feasible; (b) a derogation can only be continued for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on.		
Regulation No. 649/2012	Export and import of hazardous chemicals	NA/Uncertain	NA/Uncertain	NA/ Uncertain
Directive 2006/66/EC	Batteries	Partially - The Directive prohibits the placing on the market batteries containing mercury or cadmium with different thresholds and in different products although exemption for certain uses (e.g. military) apply.	Partially - 'Essential' exceptions to the Directive are laid out but 'essential use' concept for chemicals could potentially be explored. However, it is noted that new legislation on batteries is currently under co-decision.	No
Directive 2010/75/EU	Industrial Emissions Directive (IED)	No	Partially - Concept could be beneficial in providing an additional input to the permit condition decision-making process and to assess the need/priority to phase out organic solvents classed as CMR.	No
Regulation (EC) No 396/2005	Residues of pesticides	Partially - Temporary maximum residue levels can be included in Annex III when essential uses of PPP have been identified by a Decision to delete an active substance from, or not to include an active substance in, Annex I to Directive 91/414/EEC (placing PPP on the market).	No	No
Regulation (EU) 2017/745	Medical devices	Partially - the risks associated with the use of a medical device are compared to the potential benefits and risks must be reduced as much as possible without adversely affecting the benefit-risk ratio. The context in which the device is used	No	No

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
		and its purpose should also be taken into account.		
Regulation (EU) 2017/746	In vitro diagnostic medical devices	Partially – Annex I sets out sets out general safety and performance requirements for medical devices. This includes defining minimum performance standards and minimisation of risks related to chemicals (special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), and to substances having endocrine disrupting properties) This implies the level of risk vs level of performance needs to be considered, but no explicit mention of essentiality or components of the concept (e.g. alternatives or socio-economic assessment) are mentioned).	No	No
Directive 98/83/EC	Drinking Water	Partially - Member States may exempt from the provisions of this Directive if the quality water has no negative influence on the health of the consumers concerned and in situations where the quantity of water supplied is small.	No	No
Regulation No. 648/2004	Detergents	No	Partially - Concept could be applied within the scope of the complementary risk assessment.	No
Directive 98/24/EC	Chemical Agents (CAD)	No	No	No
Regulation (EC) No 1333/2008	Food additives	No	No	No
Regulation (EC) No 1272/2008	On classification, labelling and packaging of	No	No	No

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
	substances and mixtures (CLP)			
Directive 2004/37/EC	Carcinogens and mutagens at work	No	No	No
Directive 2008/68/EC	Inland transport of dangerous goods	No	No	No
Directive 94/33/EC	Young people at work	No	No	No
Directive 92/58/EEC	Signs at work	No	No	No
Directive 2009/148/EC	Asbestos	No	No	No
Directive 2008/98/EC	Waste Framework Directive	No	No	No
Regulation (EC) No 1013/2006	Waste shipments	No	No	No
Directive 2012/18/EU	Seveso	No	No	No
Directive 2000/60/EC	Water Framework Directive (WFD)	No	No	No
Directive 91/271/EEC	Urban Wastewater Treatment Directive (UWWTD)	No	No	No
Directive 2008/56/EC	Marine Strategy Framework Directive	No	No	No
Directive 94/62/EC	Packaging and Packaging Waste	No	No	No
Directive 75/324/EEC	Aerosol dispensers	No	No	No

Legislation number	Legislation Name (short name)	Already includes a concept of essential use or similar?	The definition and implementation of the concept could benefit, the legislation?	Prioritised?
Directive 2014/28/EU	Explosives	No	No	No
Directive 2014/68/EU	Pressure equipment	No	No	No
Regulation No 66/2010	EU Ecolabel	No	No	No
Directive 2001/95/EC	General Product Safety	No	No	No
Regulation No. 440/2008	Test methods	No	No	No
Directive 2004/9/EC	Good Laboratory Practice, a	No	No	No
Directive 2004/10/EC	Good Laboratory Practice, b	No	No	No
Directive 2002/32/EC	Contaminants in food and feed	No	No	No
Regulation 2003/2003	Fertilisers	No	No	No
Directive 92/85/EEC	Pregnant workers	No	No	No

Appendix B
Case studies

Overview

In this section, we present case studies of hypothetical examples of the application of the essential use concept to existing real-life cases of where chemicals have been restricted or authorised for use under different EU legislation.

This includes:

1. REACH restriction of cadmium – restriction
2. REACH authorisation of Cr(VI) substances – authorisation
3. The regulation of cadmium and lead under Food Contact Materials (FCM) legislation – restriction (with potential authorisation)
4. Lead in alloys under the Restriction of Hazardous Substances (RoHS) Directive – authorisation
5. Bis(2-ethylhexyl) phthalate (DEHP) in medical devices under the Restriction of Hazardous Substances (RoHS) Directive – authorisation
6. Trichloroethylene under EU Taxonomy legislation – interpretation[1]
7. Anticoagulant rodenticides under the Biocidal Products Regulation (BPR) – authorisation

[1] The potential application of the essential use concept here is not strictly speaking for the authorisation or (derogation from) restriction of chemicals as the Taxonomy legislation is not regulating the production or use of chemicals. Here the application of the essential use concept is expected to guide industry interpretation of which uses of SVHCs would be considered 'essential for the society' in the context of the Taxonomy legislation. See the full case study for a more detailed discussion.

1. REACH restriction of cadmium

Case study name	REACH restriction of Cadmium	
Introduction	This case study focuses on the existing REACH restriction for cadmium, and specifically the derogation for uses of cadmium pigments that are used for 'safety reasons'. This will investigate if the application of the essential use concept, and its specific focus on derogations for uses that are 'necessary for health/safety' would have impacted this case and if this could have made the process of considering derogations more effective or efficient. It should be noted by the reader that the comparative discussion between the 'current' and 'essential use' scenarios is based on a consideration of REACH as it is currently applied (i.e., the REACH baseline) and does not consider proposed options for REACH revision (as discussed elsewhere in this report).	
Research questions for case study	**Overall objective** – To assess how the essential use concept could have been operationalised in this situation, if applied already, and investigate how it could have impacted this case of REACH derogation from restriction e.g., improved the effectiveness and efficiency of the process, the level of protection for health/environment, legal certainty, predictability, incentives to substitution, etc. The main objective of this task is to help elaborate the horizontal concept in Task 3. Main high-level questions: ● How could the main elements of the essential use concept (necessity/criticality/lack of alternatives) have been assessed in this specific case to inform the decision? ● What are the key practical challenges in applying the essential use concept to this particular case? ● What would be the impacts if the essential use concept were applied in this case – health/environment, economic, societal? ● What key lessons can we draw from this case for implementing the essential use concept?	
Information sources and line of evidence	**Literature review**	Publicly available documents reviewed, including: ● REACH legislative text, including all implementing decisions on listing of cadmium under Annex XVII ● Information on cadmium published on ECHA website ● ECHA Opinion documents on cadmium and its compounds

Case study name	REACH restriction of Cadmium	
		• Further documents and analysis conducted by ECHA specifically relating to this derogation • Further academic literature and research (see reference list)
	Consultation	• Discussions were held with the European Commission REACH experts during initial targeted interviews with the departments and desk officers of the Commission responsible for this legislation. • Further discussion with stakeholders on the case studies during stakeholder interviews – limited input received on this specific case.
	Other Sources	N/A
Background context	**Legislation**	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This case study concerns the REACH restriction process (see Task 1 and 2 outputs), with the focus on a specific substance subject to REACH restriction (see Annex XVII, Entry 23), and the exemptions applied (see below).
	On substance (and its alternatives)	Cadmium[2] (CAS No 7440-43-9; EC No 231-152-8) and its compounds. Cadmium is a heavy metal that is known to be carcinogenic with links between occupational exposure and lung cancer having been identified. It is also highly toxic and has been associated with kidney disease and damage to the respiratory and skeletal systems (Turner, 2019)with a harmonised classification[3] of Carc. 1B and STOT RE 1. At present, there are 21 active registrations listed for cadmium under REACH[4]. Cadmium is listed on the Candidate List of substances of very high concern for Authorisation, due to the following properties: i) carcinogenic (Article 57a); ii) Specific target organ toxicity after repeated exposure (Article 57(f) - human health).[5]

[2] European Chemicals Agency, ECHA. Substance Information: Cadmium. Retrieved 2022-11-24 at: https://echa.europa.eu/en/substance-information/-/substanceinfo/100.028.320.
[3] European Chemicals Agency, ECHA. Summary of Classification and Labelling, Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Retrieved 2022-11-24 at: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/51061.
[4] European Chemicals Agency, ECHA. Registration Dossier: Cadmium. Retrieved 2022-11-24 at: https://echa.europa.eu/en/registration-dossier/-/registered-dossier/15342/1/2.
[5] European Chemicals Agency, ECHA. Candidate List of substances of very high concern for Authorisation. Retrieved 2022-11-24 at: https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dd024.

Case study name	REACH restriction of Cadmium	
	On use/function	Cadmium is widely used in a range of different applications including electronics, jewellery, polyvinyl chloride (PVC), cadmium-based pigments and brazing fillers(Turner, 2019). This case study focuses mainly on the use of cadmium in paints as this is the main aspect that is of interest regarding an exemption provided under the REACH restriction for cadmium. Cadmium pigments are stable inorganic colouring agents which can be produced in a range of brilliant shades of yellow, orange, red and maroon (Turner, 2019). It is estimated that 90% of the total volume of cadmium pigments worldwide are used in plastics and approximately 5% in ceramics.
	On the current situation	This case study is focussed on the regulation of cadmium under REACH. The regulation of cadmium has existed in EU legislation for a number of decades. One of the first steps taken by the EU towards controlling environmental cadmium pollution was Council Resolution of 25 January 1988 which took steps to limit the use of cadmium to cases where there are no suitable alternatives. The 'Cadmium Directive', Directive 91/338/EEC, built upon this Council Resolution and limited the uses of cadmium to pigments and paints, stabilisers in plastics and to cadmium plating. Cadmium and its compounds were originally added to Annex I to Directive 76/769/EEC6 in 1991 restricting its use with a number of specified derogations. When REACH was first introduced in 2006, this restriction was included as Entry 23 of Annex XVII. The existing REACH restriction for cadmium (Para 1 and 2) prohibits the use of cadmium and cadmium compounds in mixtures and articles produced from a number of synthetic organic polymers (plastic material) and in paints with codes [3208] [3209]. However, a derogation to these restrictions (Para 3) is provided for articles coloured with mixtures containing cadmium "for safety reasons". In an ECHA (2012) report it was noted that the following cadmium pigments have been identified as having been used in coloured articles for 'safety reasons': cadmium sulphide, cadmium sulphoselenide 'Orange 20', cadmium sulphoselenide 'Red 108' and cadmium zinc sulphide 'Yellow 35' and that of these, only cadmium sulphide had existing REACH registration dossiers. On the subject of this derogation, The European Commission requested ECHA (letter dated 28 September 2011) to investigate the issue of safety applications of articles coloured with cadmium to identify whether or not they are still relevant and their socio-economic implications (ECHA, 2012). In the event that any applications would still be

[6] Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.

Case study name	REACH restriction of Cadmium	
		applicable, ECHA was requested to prepare a guideline or clarification document which would describe the cases in which this derogation could be applied, in order to clarify the provision and help enforcement authorities. Following this, a Q+A entry was added for cadmium on the ECHA web page in April 2015.[7] This case study will investigate how this derogation for the use of cadmium pigments could have been defined and implemented using the essential use concept and if this would have impacted the effectiveness or efficiency of regulating this substance in this application.
Application of Essential Use Concept Criteria	**Feasibility**	In terms of scope, as cadmium is listed as an SVHC, it would constitute a 'most harmful substance' in the context of the essential use concept. This would likely be an easy/quick identification (no further evidence/burden needed compared to current situation). In terms of the application of the essential use criteria: Entry 23 under Annex XVII for cadmium includes a derogation for "safety reasons". It is not clear what originally was the reasoning or assessment carried out to justify this derogation when it was first implemented. In comparison, a key criterion under the essential use concept is to identify uses that are "necessary for health/safety", so there is some potential divergence between the two scenarios8. This opens the possibility that under the existing restriction, there could potentially be a 'broader' interpretation for the derogation than under the essential use concept. It could be envisaged that the essential use concept would be applied in a more focussed/specific way, identifying key functionality/functionalities that cadmium-based pigments provide that are considered 'necessary for health/safety' and where there are no alternatives. The justification for why this is considered 'necessary' in the context of health/safety would have been made clear, firstly in the legislative text introducing the basis of the derogation, then further complemented by associated additional guidance to make clear to industry and authorities how the derogation should be justified and assessed. In an ECHA (2012) report it was noted that some Member States had raised concerns over this derogation, indicating the "derogation is also difficult (if not impossible) to enforce, given that a company could easily claim that any cadmium in articles is used for 'safety' reasons" and that the provision was "vague and difficult to enforce". They also noted the lack of supportive information concerning technical and socio-economic aspects of this derogation.

[7] European Chemicals Agency, ECHA. Questions and answers. Retrieved 2022-11-24 at: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/825.
[8] In this case study, the two scenarios considered are, i) under the existing REACH restriction and derogation, and ii) under the essential use concept.

Case study name	REACH restriction of Cadmium	
		The restriction (and associated derogation) for cadmium had been in place for over 20 years before the ECHA Q+A clarification was issued in 2015 (see details below). It is clear from the Member State input that the derogation was not sufficiently specific and was difficult for industry, as well as authorities, to interpret, and potentially left open the risk of uses being continued on the basis of 'safety reasons' that are not strictly 'necessary'. Furthermore, it should be noted that the existing derogation does not make explicit reference to an assessment of alternatives, while the essential use concept would require a consideration of alternatives that are 'acceptable from the standpoint of environment and health'. No documentation has been identified on what assessment of alternatives was undertaken for this restriction, but it is noted that it pre-dates requirements for assessment of alternatives e.g., as part of proposals for restrictions on marketing and use of certain chemicals. In practice, the application of the essential use concept in this case could have meant a more 'granular' assessment of the uses of cadmium and its alternatives in this context, looking more closely at the specific uses and technical function provided, on possible alternatives and based on more specific and strict criteria to determine if this use is 'necessary for health or safety / critical for the functioning of society' and the lack of alternatives.
	Challenges	In terms of applying the essential use criteria, there are two key aspects, both with specific challenges: *Demonstrating necessity for health or safety / criticality for functioning of society* In order to apply the essential use concept in this case, a key requirement would be setting clear criteria for what 'necessary' for health/safety means in this context and how industry would demonstrate this. The ECHA (2012) report investigated the specific 'safety' applications for which cadmium is used and the specific function cadmium provides that is needed to ensure safety. For example, cadmium pigments were said to provide the highest achievable values for weather resistance, light fastness, heat resistance and it was noted that without cadmium pigments, a number of security applications would become less secure due to a loss of signal colour strength (fading), which may occur in outdoor conditions (e.g. on boats) or in high-temperature settings (e,g. in aircraft). Following the ECHA (2012) report, ECHA was required to prepare a new entry in the Questions and Answers for restrictions relevant to Annex XVII of REACH with an explanation of the conditions under which the derogation might apply to "improve clarity of the scope of the derogation and help with its enforcement". A Q+A entry was published on ECHA's website in June 2015 – clarifying two broad safety aspects in relation to this derogation. 1. use of a specific colour or pigment with certain properties which is necessary to prevent accidents; and

Case study name	REACH restriction of Cadmium

2. use of a specific colour or pigment with certain properties in safety equipment.

More specifically, this entry specified that the derogation in paragraph 3 of entry 23 covers current applications of articles such as:

- **Coloured wire insulation and cable jackets** used in aircraft electrical and control systems for the purpose of fire detection and extinguishing systems, flight control systems or during flight tests – noting the function of colour fastness and high-temperature resistance.
- **Outdoor safety equipment**, such as parts of rescue boats for ships (e.g., safety belts, water pockets of life rafts, canopies) and parts of safety equipment for outdoor applications (e.g. seats, reels and diverse technical parts) – noting the function of the substance (e.g. weather resistance, light fastness, heat resistance and chroma).

Furthermore, it was specified that other applications that could benefit from the derogation would need to show similar kinds of safety aspects to those described above.

It can be concluded that, based on the clarification provided by ECHA, the specific interpretation of what the 'safety reasons' are that would be covered by the derogation are broadly in line with what could be included in the elements to be included in the horizontal guidance for demonstrating a use is 'necessary for health or safety' in the context of the essential use concept (see Section 3 in Part B of this report).

Demonstrating lack of alternatives

In this case, the specific requirements in terms of lack of alternatives can be considered to be relatively clear, as industry has emphasised the need to meet required performance characteristics and safety standards (e.g., for cables to meet the 'standard' colour limits for primary colours) (ECHA, 2012). Furthermore, it was noted that changes to products used in this application would need to be certified by an agency such as the Federal Aviation Administration (FAA) or the European Air Safety Agency (EASA).

In the context of the consideration of whether a loss of performance is acceptable, it would seem logical that little or no performance loss could be accepted in these applications, on the basis of the strict performance requirements (see ECHA 2012 report).

Case study name	REACH restriction of Cadmium	
		In conclusion, on the basis of considering the different aspects of the essential use concept, it could be expected that the overall outcome would not be substantially different than how it is currently now applied and interpreted under the REACH restriction (i.e., with the 2015 ECHA clarification on the scope of the derogation). However, the legal certainty could have been better if the derogation were formulated more specifically in the legal text of the restriction on the basis of the essential use criteria. The consideration in the below sections will be on any differences in the overall effectiveness and efficiency of arriving at that decision.
Potential impact of the ESU in this case	**Administrative burden**	To some extent the level of burden, and the comparison between the two scenarios[9] is unclear. The burden is dependent on which party bears the burden of proof for justifying a derogation – either industry (if it is given the possibility to submit derogation requests) or authorities (if they propose a derogation directly in their restriction proposal). The essential use concept has been considered in this study on the assumption that industry would bear the burden of proof. Under the existing REACH restriction, the (para 3) derogation would not require individual companies to apply for a derogation, and this would not need to be assessed or approved per se. This could be seen as imposing a comparatively lower burden for industry (not needing to apply for derogation) and authorities (not needing to assess industry applications) compared to the essential use concept where individual derogations would need to be upfront assessed and proposed by authorities in their restriction proposal or applied for by industry and assessed by authorities. Given that in both cases, the burden on authorities would be maintained, the relative difference in this burden between the two scenarios is uncertain. Furthermore, it is difficult to anticipate how many company applications for derogations would need to be prepared and assessed under the essential use concept, given that the assessment is linked to specific use(s). This latter aspect would be dependent on how 'disaggregated' are the uses for which the applicant chooses to provide supporting evidence against the essential use criteria applied, i.e., how 'broad' the description of the 'use' is in the application. For example, the application for derogation may need to be supported by evidence considering different specific technical functions, or these could potentially be 'grouped' together e.g. on the basis of different types of use (outdoor safety equipment, using cables/wiring) or very specific uses (flight control systems, safety belts, seats etc). In practice, the applicant for derogation would be required to define the level of "disaggregation" or "granularity" in the use(s) covered by their derogation application and companies should define the use they request to derogate depending on for which use definition they are able to discharge their burden and proof that such use is essential. This would need to be defined on a case-by-case basis for each derogation request, therefore it is unclear if this represents a more or less burdensome process for industry.

[9] In this case study, the two scenarios considered are, i) under the existing REACH restriction and derogation, and ii) under the essential use concept.

Case study name	REACH restriction of Cadmium
	A key difference is that, in practice, the current derogation, due to its broad scope as adopted in the restriction, necessitated ECHA to perform further investigation and clarification to enable Member States to enforce this restriction, leading to additional burden on authorities. It could be envisaged that the essential use concept could alleviate the creation of burden such as this by providing clear and well-defined criteria from the outset.
Timing of procedure	As discussed in earlier sections, in terms of the 'timing' of providing clarification on the scope of the derogation and provision of guidance to industry and authorities – it can be considered that the essential use concept would have helped define and clarify this issue (i.e., defining the scope of the derogation) more quickly. It could have also provided a better predictability for companies and authorities from the start of the restriction. It is difficult to provide a comparison between the two scenarios[10] in terms of the timing of the actual application/assessment for derogations, as discussed above. However, it could be considered that the case for the use of cadmium-containing pigments in applications that are 'necessary for health/safety' would be relatively quick to identify through the essential use criteria, linked to well-defined elements to be included in the horizontal guidance 'necessary for health or safety' (see Section 3 in Part B of the this report). It is noted that in the case of the existing restriction, the derogation allowed for reasons of 'safety' does not require an assessment of alternatives. Therefore, even though it could be expected that the demonstration of lack of alternatives for these specific uses of cadmium would be fairly straightforward (i.e., if linked to specific safety standards or specifications), this would add a further step, and corresponding timing, for the overall assessment of essential use.
Simplification of the regulatory procedures	There is a number of aspects of the essential use concept that could improve the overall regulatory procedure for 'the most harmful chemicals' compared to the existing derogation: ● Although there is now a clear guidance (from the ECHA 2015 clarification) on what this derogation actually covers, it is noted this has come a long time after derogation was originally set out, and Member States have noted the period of uncertainty that had resulted. In can be envisaged that, had the essential use concept been implemented in the first instance, this would have provided greater clarity and hence greater regulatory efficiency by specifying the definition of the 'safety reasons' much earlier. ● It was noted in the ECHA (2012) report that only a small number of cadmium substances are actually used in this application (and only one that has REACH registrations). Since the essential use concept could be applied to specific chemical substances in the considered uses, this offers the potential to specify derogations only for

[10] In this case study, the two scenarios considered are, i) under the existing REACH restriction and derogation, and ii) under the essential use concept.

Case study name	REACH restriction of Cadmium	
		the specific hazardous substances used rather than 'cadmium and its compounds' more broadly, as well as for a narrower scope of use(s). • The current derogation does not specify a time limit for use of cadmium pigments for 'safety reasons'. Under the essential use concept, it is envisaged that derogations would be time limited. Industry has indicated that alternatives are not able to meet all the required performance characteristics for high temperature wire/cable, but suppliers are continuing to identify and test alternatives. This demonstrates how the implementation of a time limited derogation, as envisaged for the essential use concept could be beneficial for encouraging further development of alternatives. It should be noted that it is not clear on what basis the original (1991) derogation was made and it is unclear whether the socio-economic analysis would have played a role in the decision so it is not clear if this could be avoided.
	Predictability	As mentioned throughout this case study, clearly specified legal wording of the derogation for the 'essential' uses of cadmium in this context is a key requirement for the successful implementation and application of this derogation. It has been noted (see above) that Member States had considered the derogation, as originally defined, to be 'vague'. The ECHA 2015 Q+A entry provides more specific guidance and makes this derogation clearer and more predictable. In theory, this information should have been provided by a potential industry applicant in order to demonstrate 'essential use' and justify a derogation from the restriction under REACH. In practice, this guidance came 20+ years after the derogation for use of cadmium in paints for 'safety reasons' was first implemented, meaning that uses of cadmium for 'non-essential' uses under the justification of 'safety reasons' could possibly have occurred due to lack of 'predictability or legal certainty as to how the derogation should be interpreted and enforced.
	SMEs	Not mentioned explicitly in the documentation reviewed for this case study.
	Sector-specific	The nature of the derogation (and the specifics on where this can be applied) appear more relevant to applications in transport (marine, aviation). This is not expected to impact how the essential use concept would be implemented in legislation but could require either/both horizontal guidance (detailing the key relevant elements) and legislation-specific guidance to be made available.
	Geographic	Union-wide legislation so no/limited difference between Member States expected. Due to the international scope of this sector of use (e.g. mainly impacting transport sectors like aviation/shipping), this potentially raises the issue of compliance of non-EU users, e.g. those using cadmium on vessels that originate from outside the EU.

Case study name	REACH restriction of Cadmium
Existing gaps in knowledge	• Information not available/identified from the original restriction of cadmium and its compounds (originally listed in 1991) so it is uncertain what justification was used to define this derogation.
Key lessons learned	• This case study provides a good example of what level of granularity may be needed in terms of defining 'necessity for safety' and presents an example of where this has been applied to an existing derogation to REACH restriction. • It is unclear whether the essential use approach would have led to a different decision. However, it is noted that applying the level of detail/granularity and clarity regarding of what constitutes 'necessity for health/safety' in this case was required to address perceived ambiguity/broad scope of the existing derogation. • In helping to avoid a potential ambiguity, the essential use concept therefore offers an increased level of legal certainty and predictability from the start of the restriction, and the avoidance of continued use of a most harmful chemical in some non-essential uses under the current unspecific and broad derogation, as well as allowing Member State authorities to better enforce the restriction and derogation from it, • This is an example of where the essential use concept could potentially offer a more targeted, more specific and narrower derogation compared to the existing restriction, therefore potentially leading to a more effective and efficient elimination of the most harmful chemicals. • It is unclear whether the socio-economic analysis would have played a role in the decision so it is not clear if this could be avoided. At the time the restriction was introduced, there were less stringent expectations for SEA in place.
References	ECHA (2012). The Use of Cadmium and its Compounds in Articles Coloured for Safety Reasons (Derogation In Paragraph 3 Of Entry 23 Of Annex XVII). Accessed at: https://echa.europa.eu/documents/10162/17233/cadmium_articles_coloured_safety_reasons_201211_en.pdf/8bfae53a-d988-4568-b3bd-992790a718c9 Turner, A. (2019). Cadmium pigments in consumer products and their health risks, Science of the Total Environment, 20 (657):1409-1418. Doi: 10.1016/j.scitotenv.2018.12.096.

2. REACH Authorisation of Cr(VI) substances

Case study name	**REACH Authorisation of Cr(VI) substances**	
Introduction	This case study considers the use of Cr(VI) substances in the context of two existing REACH authorisations. For purposes of this case study, the focus is on specific authorisations for the use of strontium chromate in specific application in the aerospace sector. The case study investigates the process for assessing the application for a REACH authorisation and compares this to the situation that could occur if the essential use concept had been used to consider authorisations for the use of this substance in this application. It should be noted by the reader that the comparative discussion between the 'current' and 'essential use' scenarios is based on a consideration of REACH is it is currently applied.	
Research questions for case study	**Overall objective** – To assess how the essential use concept could have worked in the case of the authorisation of Cr(VI) substances, if applied already, and investigate how it could have impacted this case of authorisation e.g., as regards the effectiveness and efficiency of the process, the level of protection for health/environment, legal certainty, predictability, incentives to substitution, etc. Main high-level questions: ● How could the main elements of the essential use concept (necessity/criticality/lack of alternatives) have been assessed in this specific case to inform the decision? ● What are the key practical challenges in applying the essential use concept to this particular case? ● What would be the impacts if the essential use concept were applied in this case (i.e. to a granted authorisation for certain specific uses of Cr(VI) substances) – health/environment, economic, societal? ● What key lessons can we learn from this case for implementing the essential use concept?	
Information sources and line of evidence	**Literature review**	Key publicly available documents reviewed: ● Legislative text and implementing decisions

Case study name	REACH Authorisation of Cr(VI) substances	
		• ECHA documents and opinions of the RAC/SEAC as well as documents submitted as part of the application e.g. alternatives assessment and socio-economic analysis. • Further academic literature and research.
	Consultation	• Discussions were held with the Commission REACH experts during targeted interviews with the departments and desk officers of the Commission responsible for this legislation. • Inputs from relevant trade associations [confidential] during stakeholder interviews and further written inputs received subsequently.
	Other Sources	This case study has been informed by [ongoing, not yet published] research being conducted relating to the essential use concept and existing REACH authorisation conducted by researchers at the University of Stockholm.
Background context	**Legislation**	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This case study concerns the REACH authorisation process, with the focus on two specific applications for authorisation (see below).
	Substance	This case study concerns the use of hexavalent chromium (Cr(VI)) substances, specifically strontium chromate[11] (EC No 232-142-6, CAS No 7789-06-2). Strontium chromate has harmonised classification as Carc. 1B.[12]
	On use/function	Strontium chromate is added to formulations, such as paints, primers and specialty coating mixtures, which are applied to the surface of aircraft and spacecraft parts, and satellite components to perform a range of technical functions (ECHA, 2016). These coatings are applied on a part's surface to protect the part from corrosion, thermal

[11] European Chemicals Agency, ECHA. Substance Information: Strontium chromate. Retrieved 2022-11-24 at: https://echa.europa.eu/substance-information/-/substanceinfo/100.029.220.
[12] European Chemicals Agency, ECHA. Summary of Classification and Labelling, Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Case study name	REACH Authorisation of Cr(VI) substances	
		shock and wear or to improve adhesion between metals, as well as to bond metallic and non-metallic parts (e.g. surface coatings applied on top of the bond coating). They may be applied during production, maintenance or repair. The key function of strontium chromate in the surface coatings is corrosion inhibition. For example, strontium chromate functions as a corrosion prevention and inhibiting agent in coatings applied to metals and alloys, including aluminium, magnesium, steel, cobalt, nickel and titanium.
	On the current situation	Strontium chromate was included on the Candidate List of substances of very high concern in June 2011. It was identified as a substance meeting the criteria of Article 57 (a) of REACH owing to its harmonised classification as carcinogen category 1B and is included in Annex XIV (Authorisation List), hence its uses are subject to authorisation requirement. A group of 28 companies formed a consortium - Chromium VI Compounds for Surface Treatment REACH Authorization "CCST" - to develop applications for authorisation of uses of the most important Cr(VI) substances. In this case, an Application for Authorisation (AfA) was submitted for 2 uses in December 2016 by Akzo Nobel Car Refinishes B.V. and 9 other applicants[13] and was assessed by ECHA's scientific committees ("RAC" Risk Assessment Committee and "SEAC" Socioeconomic Analysis Committee). A decision partially granting an authorisation for these uses (through the SEA route) was published (European Commission, 2020) on 16 April 2020 (C(2020)2076). In this case the use of strontium chromate is authorised for 2 uses: ● Use 1 - the "formulation of mixtures" (including strontium chromate) intended exclusively for use 2; and ● Use 2 - the "application of primers and specialty coatings (containing strontium chromate) in the construction of aerospace and aeronautical parts, including aeroplanes, helicopters, spacecraft, satellites, launchers, engines, and for the maintenance of such constructions for the aerospace sector in which any of the following key functionalities is required: corrosion resistance, adhesion of paint / compatibility with binder

[13] AKZO Nobel Car Refinishes B.V. Analysis of alternatives: Application of paints, primers and specialty coatings containing Strontium chromate in the construction of aerospace and aeronautical parts, including aeroplanes / helicopters, space craft, satellites, launchers, engines, and for the maintenance of such constructions, as well as for such aerospace and aeronautical parts, used elsewhere, where the supply chain and exposure scenarios are identical. Retrieved 2022-11-24 at: https://echa.europa.eu/documents/10162/d93ccf53-2682-44d4-8c93-920d0f48269f.

Case study name	REACH Authorisation of Cr(VI) substances	
		system, layer thickness, chemical resistance, temperature resistance (thermal shock resistance), compatibility with substrate or processing temperatures". The justification for the decision: in accordance with Article 60(4) of REACH was that the socioeconomic benefits outweigh the risk to human health from the uses of the substance and there are no suitable alternative substances or technologies, with regard to the scope of the use as limited in the decision with reference to the above-mentioned key functionalities (as it was considered necessary to limit the description of the use due to the broadly defined scope of the use in the application). This case study will investigate how the essential use concept could have been applied in this specific case and how this could have impacted the situation in terms of the overall effectiveness and efficiency of the regulation of hazardous chemicals.
Application of Essential Use Concept Criteria	**Feasibility**	In terms of the scope of the essential use concept, strontium chromate is listed as a SVHC so would constitute a 'most harmful' substance in the context of the chemicals strategy. It would likely be an easy/quick check whether this substance falls under the scope of the most harmful substances (no further evidence/burden needed compared to current situation). In terms of the application of the essential use criteria: Strontium chromate is a 'non-threshold' substance so currently an authorisation for its uses may only be granted via the so called socio-economic (SEA) route. This case study considers the application of the essential use criteria for assessing the justification for an authorisation for the uses of strontium chromate, in place of the existing authorisation criteria set in Article 60(4). These required that the authorisation decision was based on the consideration that 'benefits of using strontium chromate outweigh the risk' considering a socio-economic analysis and that there are no suitable alternatives, on the basis of the analysis of alternatives. Considering the key components of the essential use criteria: *Necessary for health/safety' and 'critical for the functioning of society:* The aspect of 'necessity' and 'criticality' as defined in the essential use concept is not currently considered explicitly in the REACH authorisation process, with the assessment being based on a benefit-risk comparison of the continued use of the substance, considering socio-economic aspects. For this application, the socio-economic benefits assessed were e.g. avoided loss of revenues and profits, relocation costs, social impacts associated with loss of employment, loss in product quality, loss of aerospace related know-how within the EEA and the loss of

Case study name	REACH Authorisation of Cr(VI) substances

Europe's independent access to space (CCST Consortium, b). For a given application for authorisation, a careful assessment of whether and how these aspects relate to 'necessity' and 'criticality' (see Section 3 of Part B to this report) would need to be made.
There are functions provided by the use of strontium chromate in the products used in this sector that would meet a criterion for demonstrating 'necessary for health/safety' or 'critical for the functioning of society'. It can be expected that demonstrating how the key functionalities provided[14] deliver specific safety performance standards would be relatively simple and would not be vastly different from the existing authorisation.

For example, in the existing application for authorisation, the applicant stated that "Cr(VI)-based coatings are specified in the aerospace sector primarily because they provide superior corrosion resistance and excellent adhesion. These characteristics and the quality of the product are essential to the safe operation and reliability (airworthiness) of aircraft and spacecraft which operate under extreme environmental conditions".

If the essential use concept were to be used, the questions this raises are, a) at what level of detail/granularity this would be applied, b) what information would need to be provided to demonstrate compliance with the criteria. For example, this could include detailing what information provided as part of the current application for authorisation is or is not required and what information that is not currently required under the SEA route of authorisation would be needed to demonstrate criticality/necessity and lack of alternatives).

Lack of available alternatives:

The absence of suitable alternatives is one of the conditions for granting authorisations under the SEA route for REACH under Article 60(4) so it could be broadly considered that there would not be a substantial difference between a part of the existing authorisation process (guided by Article 60(4)) and the process under the essential use concept.

For example, key information, particularly on the technical feasibility of alternatives has been provided by the industry applicants in this case. Indeed, a number of alternatives have been considered, including:

- Epoxy/PU-based primers with Cr(VI)-free inhibitors
- Classical corrosion inhibitors based on phosphate, silicate, pH buffering additives
- Zinc-based corrosion inhibitors

[14] Including, for example, corrosion resistance, adhesion of paint / compatibility with binder system, layer thickness, chemical resistance, temperature resistance (thermal shock resistance), compatibility with substrate or processing temperatures.

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As discussed above, in the assessment of alternatives, a number of key functionalities provided by strontium chromate were identified in order to limit the scope of the granted authorisation (when compared to the use applied for). This was necessary to address the uncertainties of the broadly defined scope of the use by the applicant and limit it to the scope for which the absence of suitable alternatives was deemed to be demonstrated. For example, it was noted that for use in primers applied by aerospace and defence sector, the following key functionalities or properties were seen as necessary for the intended use: corrosion resistance, active corrosion inhibition, adhesion promotion, thermal shock resistance and chemical resistance.

Industry emphasised that Cr(VI)-based coatings are specified in the aerospace sector primarily because they provide superior corrosion resistance and excellent adhesion, also at elevated temperatures. Industry applicants noted that these characteristics and the quality of the product are essential to the safe operation and reliability (airworthiness) of aircraft and spacecraft which operate under extreme environmental conditions, and that these structures are extremely complex in design, containing millions of highly specified parts, many of which cannot be easily inspected, repaired, or removed (CCST Consortium, a). The SEAC assessment concluded that the alternatives considered are not suitable for all applications covered by the use applied for (with the further specifications mentioned below) and would not meet the strict performance requirements for regulatory approval.

Furthermore, it was noted that the alternatives need to meet strict performance criteria necessary for regulatory compliance in the aeronautics and aerospace industries (e.g. derived from EU Regulation No 216/2008 in Europe) to ensure airworthiness requirements. It was also noted that each coating type and material is different because it must meet individual functionalities and performance standards particular to a specific design.

Overall, it can be broadly considered that, with the information available for the existing authorisations for strontium chromate, it could be concluded that this case would meet the criteria for ‘essential use’, i.e. information presented by the applicants seems to demonstrate that the use (as limited in the authorisation) is essential because the use is necessary for safety and there are demonstrably no alternatives that fulfil the necessary function(s) of strontium chromate at an acceptable level of performance and which are acceptable from the standpoint of health/environment.

In the context of the essential use criteria for alternatives, it should be noted that in the existing Application for Authorisation, the applicant considered alternatives that would be suitable for all applications within the scope of the use but does not seem to consider different alternatives for different specific applications. Therefore, as a consequence of the broadly defined scope of the use applied for in this case, and the generic approach of the applicant in the analysis of alternatives, this approach cannot exclude that there are ‘coating applications’ using strontium chromate, where substitution is already feasible or will become so in the short-term, as concluded by

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		SEAC. That is why the scope of the authorisation has been limited and authorisation only granted partially (see title and article 1 of the partial authorisation). In the assessment of alternatives, the industry applicant(s) noted that, while the use of strontium chromate may be specified at different points in a coating system, it cannot be entirely replaced without impacting the technical performance of the final article, and that while coating systems have been developed to substitute chromates in some parts of some coating systems, no complete Cr(VI)-free coating system, providing all the required properties to the surfaces of all articles in the scope of this application, is available. Overall, the applicant's assessment of alternatives argued that, due to its unique functionalities and performance, it is challenging and complex to replace surface treatments based on Cr(VI) substances in applications that demand superior performance for corrosion and/or adhesion to deliver safety over extended periods and extreme environmental conditions. The SEAC opinion (ECHA, 2016) concluded that there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant, while the RAC opinion (ECHA, 2016) confirmed that there appear not to be any suitable alternatives that further reduce the risk. However, it was also noted that the analysis of alternatives provided by the applicant does not sufficiently differentiate between the various coating applications which is considered by SEAC a shortcoming of the analysis.
	Challenges	There are a number of key challenges for applying the essential use concept to assess authorisations for these uses (use 1 and 2, see above): • **Defining the specific elements for 'necessary for health/safety' and 'critical for the functioning of society' for determining essential use** – As discussed above, this aspect would likely be a markedly different means of assessment compared to the current REACH authorisation process. In practice, this would mean clear horizontal guidance, defining the key elements, would be needed for industry applicants to follow and clarification on what data would be required to support or justify authorisation and for authorities to assess the requests. It could be considered that the justification for 'necessary for health/safety' and 'critical for the functioning of society' is relatively easy to demonstrate in this case, on the basis of the strict/regulatory performance requirements linked to uses relevant to safety in civil aviation. It would need to be established whether the information currently included in the application for authorisation would be sufficient to support an application for authorisation under the essential use concept or whether and, if so, which further evidence would be required. Input from one industry association suggested that the key challenges would have been the same as for the authorisation itself due to the complexity of the supply chain which is partially in and outside the EU. • **Establishing the appropriate level of 'granularity' and of disaggregation for the uses assessed against the essential use criteria** – As discussed above, the current REACH authorisation covers a

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		number of different technical functions and specific uses in one authorisation. A key question is whether all the functions are strictly 'essential'. The essential use concept could present the opportunity to focus this on a more targeted, specific basis. However, the key question will be to determine how detailed or 'granular' the uses may need to be disaggregated, which in turn will determine how detailed the assessment needs to be. On the one hand, this presents the chance to identify specific 'non-essential' uses where specific functions are shown either to be non-critical/ not necessary or where there are available alternatives. On the other hand, making this too specific could make the process impractical/overly-burdensome for industry and authorities. For example, in this case, it is noted in the industry assessment, that the authorisation covers thousands of different aircraft parts. If an assessment was required for all functions and equipment individually, it would be difficult/impossible to operate in practice. As noted above, a more-granular assessment could be applied (or required) under the current system, without application of an essential use concept. • **Establishing acceptable 'loss of performance' for alternatives in this use** – In this case, it could be expected that minimal/no loss of technical performance by alternatives would be accepted / deemed 'suitable' on the basis of the strict performance requirements. The SEAC opinion (ECHA, 2016) notes that, for the sector covered by the application for authorisation, complex airworthiness and approval processes need to be considered, and in order for alternatives to be industrialised and implemented, these may need to undergo qualification and certification procedures first. The SEAC opinion notes that the applicant did not provide sufficient information to distinguish between type-certification by a regulatory body (e.g. of aircraft engines) and other qualification and certification steps. Again, this would raise the question of whether the (non) acceptability of the loss of performance applies to <u>all</u> the technical functions covered by the strontium chromate in this application.
Potential impact of the ESU in this case	**Administrative burden**	If the essential use concept is implemented in place of the existing SEA route for authorisation, this could result in a reduction in overall administrative burden. It can be envisaged that this could avoid the need to provide much of the socio-economic data (e.g. loss of revenues and profits, relocation costs, social impacts associated with unemployment etc) as part of the application. However, in practice, the relative difference in administrative burden will depend on the specific new data requirements needed to demonstrate necessity/criticality, and hence the work required to prepare and assesses the applications. In this particular case, the preparation and assessment of requests as well as decision making process may be relatively straightforward as this is a heavily regulated sector where required performance is linked to the strict safety requirements/standards. It is expected that the overall data requirements, and associated burden for the assessment of alternatives would be broadly similar between the two systems. In both cases, it is expected that the ECHA guidance could be used as a starting point to develop a new guidance on the essential use concept to guide this part of the assessment. It

Case study name	REACH Authorisation of Cr(VI) substances	
		remains an open question whether the level of detail expected in analysis of alternatives would be the same, or be more or less stringent, than under the current system. It is noted that as part of introducing the essential use concept, it is expected that a new guidance would need to be developed, both horizontal guidance for the essential use criteria, but also at legislation level to inform implementation for this specific use.
	Timing of procedure	When applying the essential use concept, if it is demonstrated that the use of strontium chromate in the aircraft components is necessary for safety, and there are no available alternatives, then this confirms that it is an essential use of strontium chromate. In terms of the assessment of necessity/criticality, it could be envisaged that this aspect could be carried out relatively quickly, compared for example to a full SEA route of authorisation, and that the screening steps for applying the essential use concept could apply here to make the process relatively more rapid. In terms of the assessment of alternatives, there would not likely be a significant difference between the two systems. As this is likely to be the main time burden for the process as a whole for industry, this could indicate there may be no major difference in overall timing of an individual authorisation if based on the essential use concept.
	Simplification of the regulatory procedures	Both the existing authorisation approach and the essential use concept focus on the use of a specific SVHC/MHS so there is no difference in the scope of the authorisation in terms of chemical substances restricted. In terms of the necessity/criticality assessment, overall it is expected that this element of the essential use approach could result in a more efficient regulatory process (compared to the existing SEA-based approach) in cases where it can be easily demonstrated that the use is delivering a clear function for public safety – see discussion above. However, in other uses (currently covered by REACH authorisations) this may not be as clear-cut so could potentially also be a longer and/or controversial process in certain cases. In terms of the assessment of alternatives, it can be considered that the efficiency of the process would be broadly the same under the essential use approach as it was in this specific case. Input from one industry association suggested that a more holistic approach (and not on a company basis) could be more efficient but also noted this can be also fulfilled without the essential use concept (i.e. via upstream applications for authorisation). Ultimately, looking at the alternatives at sectorial level addresses already the question of the functionality and of the criticality of the substance for the protection of health, the environment and

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		functioning of society. It is considered that, in this Cr(VI) case, it is clear that the use of Cr(VI) is necessary/critical for safety reasons in aerospace, and this was also demonstrated in the applications for Authorisation.
	Predictability	It could be perceived that moving from a 'tried and tested' SEA-based approach for REACH authorisations, to a different approach under the essential use concept could present potential risk regarding lack of predictability. In practice, as the existing ECHA guidance on alternatives assessment is likely to be the start point under both systems for the assessment of alternatives, there may not be a significant difference in that respect. It is noted that as part of the essential use concept, it is expected that a new guidance on alternatives assessment would need to be developed. In terms of the assessment of 'necessity/criticality', the application of the essential use concept would need to be accompanied by clear horizontal guidance, with further definitions to inform what is covered by the criteria of 'critical'/'necessary' to enable industry applicants to fully understand the process and the information requirements to demonstrate the use is 'necessary/critical'.
	SMEs	It is noted that, in this case the application for authorisation was developed by a relatively large conglomerate of companies that collaborated on a joint submission. Therefore, the application was aided by the combined resource, expertise and finances of several larger companies. It is unclear how smaller companies with fewer resources and know-how could have navigated the process.
	Sector-specific	This case was specifically related to use in the aerospace sector. It is likely that, similar to the existing authorisation process, the uses receiving an authorisation under the essential use concept would be specific to use in this sector.
	Geographic	The case relates to Union-wide legislation so no/limited difference between Member States is expected. Due to the international nature of this sector (i.e. aviation), this potentially raises the issue of compliance of non-EU users.

Case study name	REACH Authorisation of Cr(VI) substances
Existing gaps in knowledge	• The specific elements outlined for the horizontal criteria of the essential use concept, and how 'granular' the application would need to be are yet to be fully defined – see Section 1,3 in Part B for the specific discussion and recommendations on this point. • The specific definition for the 'acceptability of alternatives from the standpoint of health and the environment' is yet to be fully clarified – see Section 3 in Part B of this report for the specific discussion and recommendations on this point.
Key lessons learned	• Depending on precisely what information needs to be provided by applicants to demonstrate a use is 'necessary for health/safety' or 'critical for the functioning of society' in this case, the essential use concept could offer a more efficient and streamlined approach to considering authorisations. If applied in place of the existing SEA-route process, this could remove the need for data on several socio-economic aspects that would not be relevant for the essential use concept. • Furthermore, as shown in this case study, in relatively clear cases the information needed for demonstrating necessity/criticality (as set out in the specific elements described in Section 3 of this report) do not necessarily go beyond the information in the current applications for authorisation. This could potentially lead to a more efficient and streamlined process. • This case study is an example of an existing authorisation that covers a wide range of different specific uses/functions for a hazardous substance, some of which are likely to be considered critical/necessary, however this may also cover some non-essential uses. The application of the essential use concept could therefore potentially offer a more targeted, more specific and narrower derogation compared to the existing authorisation, therefore potentially leading to a more effective an efficient elimination of the most hazardous chemicals. • In this respect, the essential use concept could also reduce or remove any potential ambiguity, with corresponding increased level of legal certainty and predictability and the avoidance of continued use of a MHC most hazardous chemical in some non-essential uses under the unclear and broad derogation. • In this case, it is demonstrated that multiple functionalities are provided by the same substance in an application that would be considered 'necessary/critical' on the basis of the need to meet strict safety standards in civil aviation. • The assessment of alternatives process is considered to be broadly similar in both systems so no major difference in the overall effectiveness or efficiency of this aspect is expected. • Overall, in this case, applying the essential use concept instead of the SEA-based approach could be expected to lead to the same or similar decisions being reached on granting of authorisations, but with reduced time/resources for the applicants and ECHA committees on the SEA. Different decisions might be reached if more specific/granular information were to be considered for less aggregated individual uses, but this would not necessarily follow simply as a result of applying the essential use concept.

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References	CCST Consortium (a). Analysis of Alternatives Report, Available at: https://echa.europa.eu/documents/10162/d93ccf53-2682-44d4-8c93-920d0f48269f. CCST Consortium (b). Socio-economic analysis Report, Available at: https://echa.europa.eu/documents/10162/cf8afeb0-bc9c-4199-bf47-921157620d22. ECHA (2016). Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) Opinion report - https://echa.europa.eu/documents/10162/170ba6ad-e903-ce62-52d0-7c68bb8cd2ea#:~:text=Based%20on%20studies%20which%20show,are%20included%20in%20the%20RAC European Commission (2020). C(2020) 2076 final, COMMISSION IMPLEMENTING DECISION of 16.4.2020 partially granting an authorisation for certain uses of strontium chromate under Regulation (EC) No 1907/2006 of the European Parliament and of the Council (Akzo Nobel Car Refinishes B.V. and others).

3. The regulation of cadmium and lead under Food Contact Materials (FCM) legislation

Case study name	**Regulation of cadmium and lead under Food Contact Materials (FCM) legislation**
Introduction	This case study focusses on the use of cadmium and lead in ceramic and vitreous food contact materials (FCMs). The case study looks at the practical challenges experienced in terms of revising the permitted migration limits for these substances under existing FCM legislation, and if/how the essential use concept would have impacted this situation.
Research questions for case study	**Overall objective** –It is important to note that this case study is distinct from other case studies presented in this section, as it focusses on an example of where the need for a restriction for the 'most harmful chemicals' has been identified, but a restriction has not yet been put in place (as detailed below). This case study investigates if/how the application of the essential use concept could have been more effective in achieving this compared to the existing situation. It should also be noted that this case is currently ongoing and a final 'decision' has not yet been made. Main high-level questions: ● How could the main elements of the essential use concept (necessity/criticality/lack of alternatives) could be assessed (in this specific case)? ● What are the key practical challenges in applying the essential use concept to this particular case? ● What would be the impacts if the essential use concept were applied in this case – health/environment, economic, societal? ● What key lessons can we draw from this case for implementing the essential use concept?
	Literature review Publicly available documents reviewed, including:

Case study name	**Regulation of cadmium and lead under Food Contact Materials (FCM) legislation**	
Information sources and line of evidence		• Legislative text[15] and relevant JRC reports (see reference list). • The European Commission (2019) Inception Impact Assessment[16] on migration limits for lead, cadmium, and the stakeholder consultation inputs submitted for this[17]. • The EFSA Opinion documents on lead and cadmium. • Further academic literature sources.
	Consultation	• Targeted interviews with the departments and desk officers of the Commission responsible for this legislation. • Inputs during stakeholder consultation, specifically the stakeholder interviews. • Specific inputs from interviews with Cefic and EFSA on this case study.
	Other Sources	N/A
Background context	**Legislation**	This case study relates to legislation covering the use of chemicals in food contact materials, specifically the 1984 Directive relating to ceramic articles intended to come into contact with foodstuffs.[18]
	On substance (and its alternatives)	**Cadmium (CAS No 7440-43-9; EC No 231-152-8)**

[15] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
[16] European Commission. Inception Impact Assessment. Retrieved 2022-11-24 at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=PI_COM:Ares(2019)3505623&from=EN.
[17] European Commission. Food safety – heavy metals in ceramic, glass and enamelled table and kitchenware. Retrieved 2022-11-24 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2074-Food-safety-heavy-metals-in-ceramic-glass-and-enameled-table-and-kitchenware_en.
[18] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

Case study name	Regulation of cadmium and lead under Food Contact Materials (FCM) legislation

- Cadmium is listed on the REACH Candidate List of substances of very high concern for Authorisation, due to the following properties: i) carcinogenic (Article 57a); ii) Specific target organ toxicity after repeated exposure (Article 57(f) - human health)[19]
- Cadmium has a harmonised classification as Carc. 1B and STOT RE 1[20].
- Uses of cadmium are restricted under Annex XVII to REACH[21].
- Cadmium is not included in the Annex I (Union list) of substances permitted to be intentionally used in the manufacture of plastic layers in plastic food contact materials under FCM legislation and is restricted in Annex II to that Regulation, including an SML ND (LOD 0,002).[22]
- Council Directive 84/500/EEC[23] relating to ceramic articles intended to come into contact with foodstuffs specifies restrictions on the level of cadmium transferred into food from different categories of ceramic articles. This is the main focus of this case study.

Lead (CAS No 231-100-4; EC No 7439-92-1)

- Lead is listed on the Candidate List of substances of very high concern for Authorisation, due to the following properties: Toxic for reproduction (Article 57c)[24]
- Lead has a harmonised classification as Repr. 1A[25].

[19] European Chemicals Agency, ECHA. Candidate List of substances of very high concern for Authorisation. Retrieved 2022-11-24 at: https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dd024.
[20] European Chemicals Agency, ECHA. Summary of Classification and Labelling, Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Retrieved 2022-11-24 at: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/51061.
[21] European Chemicals Agency, ECHA. Substances restricted under REACH. Retrieved 2022-11-24 at: https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2518.
[22] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.
[23] Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.
[24] European Chemicals Agency, ECHA. Candidate List of substances of very high concern for Authorisation. Retrieved 2022-11-24 at: https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e182607ea6.
[25] European Chemicals Agency, ECHA. Summary of Classification and Labelling, Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Retrieved 2022-11-24 at: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/51061.

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	• Uses of lead are restricted under Annex XVII to REACH[26] with exemptions provided, for example for uses in crystal glass (para 4) and uses in the scope of FCM legislation[27] (para 7). • Lead is not included in the Annex I (Union list) of substances permitted to be intentionally used in the manufacture of plastic layers in plastic food contact materials under FCM legislation and is restricted in Annex II to that Regulation, including an SML ND.[28] • Council Directive 84/500/EEC relating to ceramic articles intended to come into contact with foodstuffs specifies restrictions on the level of lead transferred into food from different categories of ceramic articles. This is the main focus of this case study.
On use/function	This case study focusses on the use of cadmium and lead in ceramic and vitreous food contact materials (FCMs), for example tableware and kitchenware such as plates, cups, glasses, bowls or oven trays. Metals such as lead and cadmium have been used for many decades in the production of these materials for technical purposes (e.g. to give shine, durability) or decorative purposes (e.g. to provide colours). Industry has indicated that ceramic colours must have special properties for their use and fixing on tableware (European Commission, 2019). One important property specified with reference to these metals for this application is temperature stability.[29] For example, there is need for the pigments used to be stable at temperatures required for firing ceramicware (750 to 1450°C) (Turner, 2019).
On the current situation	The background to this particular case is set out in detail in the European Commission (2019) Inception Impact assessment. In brief:

[26] European Chemicals Agency, ECHA. Substances restricted under REACH. Retrieved 2022-11-24 at: https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e1807e30a6.
[27] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
[28] European Chemicals Agency, ECHA. Candidate List of substances of very high concern for Authorisation. Retrieved 2022-11-24 at: https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807dd024.
[29] European Commission. Feedback from: Eurocolour e.V. Retrieved 2022-11-24 at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2074-Food-safety-heavy-metals-in-ceramic-glass-and-enameled-table-and-kitchenware/F465066_en.

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Directive 84/500/EEC (Article 2) sets out the rules that specify the maximum quantities of lead and cadmium allowed to migrate from ceramic articles into foodstuffs. It also instructs manufacturers and importers to draw up a declaration that documents compliance of the article with the current legislation on ceramic articles.

However, in 2009 and 2010 the European Food Safety Authority (EFSA) published new scientific advice on the health effects of lead (EFSA, 2010) and cadmium (EFSA, 2009) in food. It was noted that, for lead and cadmium, adverse effects occur well below levels currently set out in the Directive and these metals migrate from a significant number of ceramic and vitreous FCMs in toxicologically relevant amounts (European Commission, 2019), EFSA concluded that exposure to lead and cadmium should be significantly reduced and noted that dietary exposure is the main source of exposure to these heavy metals.

In the light of the new scientific evidence from EFSA, some Member States noted that the existing migration limits for lead and cadmium in the Directive would not provide sufficient protection of exposure for consumers. Hence, they have requested that the limits are lowered to safe levels in light of the new scientific evidence.

In practice, it has not been possible to revise migration limits (now 10+ years since the EFSA findings). A key reason for this has been the potential (disproportionate) impact this would place on smaller artisanal manufacturers of these products, where it is generally more challenging to comply with stricter migration limits due to the burden and cost associated with testing requirements and difficulty in finding viable alternatives in this application (European Commission, 2019).

The Commission has launched an 'Initiative on ceramic and vitreous FCMs[30]. In May 2019, the Commission published a roadmap outlining an initiative to lower migration limits for heavy metals in ceramic, glass, and enamelled FCMs. The policy options proposed in the roadmap include the establishment of "appropriate protective migration limits for lead, cadmium and possibly other heavy metals, in ceramic and vitreous food contact materials. Where no protective migration limits could be set, the possibility of bans on certain metals for certain uses will also be considered.

[30] European Commission. Initiative on ceramic and vitreous FCMs. Retrieved 2022-11-24 at: https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials/revision-eu-rules/initiative-ceramic-and-vitreous-fcms_de#:~:text=Initiative%20on%20ceramic%20and%20vitreous%20FCMs%20New%20initiative,nickel%20from%20ceramic%20and%20vitreous%20food%20contact%20materials.

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		This case study will consider how the process of improving health protections related to the use of lead and cadmium in this use would have been potentially different if the essential use concept had been used to regulate these substances.
Application of Essential Use Concept Criteria	**Feasibility**	In terms of the scope of the essential use concept, as both cadmium and lead are classified as SVHCs and have harmonised C&L hazard classification, each can be considered as a 'most harmful substance' in the context of the Chemical Strategy for Sustainability (CSS). It is expected that no/limited additional information would likely be needed to demonstrate this in this case. It is noted that currently there is not a derogation/authorisation permitted for lead and cadmium in these uses; it has not been feasible to apply a restriction (through stricter migration limits) despite the clear indication this would be justified (see above). Here we consider how this situation may differ under the essential use concept. In terms of the essential use criteria: In the case of cadmium, as discussed above, cadmium compounds are some of only a few pigments that provide certain intense colouring and that will be stable at temperatures required for firing ceramicware (i.e. 750 °C to 1450°C). In the case of lead, the use of lead oxide is considered a quality requirement for glass, which is set by EU legislation (Council Directive 69/493/EEC, 'the crystal Directive') which requires that glass can only be named 'lead crystal' when it contains at least 24% of lead oxide) (Hynes and Jonson, 1997). A number of specific properties impaired by lead have been highlighted in relation to the use in crystal glass (Hynes and Jonson, 1997). This includes density and refractive index, properties used for classification of crystal glasses, as well as promoting a low deformation temperature, useful for low temperature glazing procedures. With respect to the criteria, and the specific elements defined for 'necessity for health/safety' or 'critical for the functioning of society', it is difficult to envisage a basis for which the use of cadmium or lead in this use would fulfil the criteria. The function provided is being used largely to achieve decorative or aesthetic results, and in the case of lead in crystal glass, there is an additional functionality relating to the overall durability and performance of a FCM product/article, notwithstanding the potential availability of safe alternatives. It could be expected, therefore

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that under the essential use concept, a narrower or more well-defined criteria would result in the straightforward restriction of these most hazardous chemicals in these uses.

From the evidence presented in the inception impact assessment (European Commission, 2019) and the industry inputs to the associated consultation, there do not appear to be aspects of this function that relate to, for example, maintaining levels of hygiene, food preservation or public health etc that would demonstrate these chemicals are needed for an 'essential' use. This raises the key question, within the context of this project, regarding how the elements of the horizontal guidance for further detailing how 'necessity' and 'criticality' would be defined and how applicants would demonstrate this in this case (see Section 3 in Part B of this report).

It is noted above that in the case of lead glass, this use links to a legal requirement under existing EU legislation, which could also potentially be considered an aspect in terms of ensuring coherence with other EU law and strategies. However, as this does not have a clear link to wider benefit for the functioning of society, or to health or safety, this may not be strictly considered 'necessary/critical'. It is also not a requirement for industry to market products as 'crystal', merely an established legal definition exists for the naming of products as such.

In this respect, the main aspect of relevance could be the ''criticality' linked to cultural/heritage grounds, as it has been noted that "these oxides are often used in artisanal and traditional techniques to manufacture products that may have a special regional or local cultural value" (European Commission, 2019) and industry inputs raised the issue of 'significant impact expected to traditional and artisanal production'. Indeed, there is a potential concern that smaller companies producing traditional ware (Wedgewood, Delft, Crystal glass) may not be able or even want to comply with stricter limits because they would lose the added value of their products (e.g. not being able to compete with cheaper products from China).

A clear definition of the elements in the horizontal guidance for the "criticality for the functioning of society" within the essential use concept (as set out in Section 3 of Part B of this report) would inform the consideration of whether and which particular links to 'cultural heritage', e.g. those for maintaining and protecting existing monuments/artifacts/landscapes, could qualify a use to be considered "critical for the functioning of society". In this case the emphasis would be on current ongoing practices with perceived cultural or artisanal value.

In terms of the criteria for the (non-)availability of alternatives, this would also need to be demonstrated in accordance with the essential use criteria, for the use of cadmium and lead for these specific applications.

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Some industry input to the inception impact assessment consultation indicated that for these applications where high temperature stability pigments are needed, manufacturers, particularly small-scale artisanal users are unable to source suitable alternatives or could incur high costs.

In the case of ceramic glazes - depending on the specific definitions applied in the assessment of alternatives, for example, on the technical feasibility/performance needed to be considered 'acceptable', it is noted that there are potential alternatives in these applications that have been identified (Lehman, 2002). For example, uses of other metals such as bismuth, zinc and strontium have been noted, as well as use of alkali borosilicate [ABS] formulations (Lehman, 2002). However, some technical drawbacks were raised with ABS formulations e.g. relating to firing temperatures and defect rates, meaning they would not be seen as 'acceptable' in the context of the essential use concept. The specific 'feasibility' of the alternatives in the specific applications being considered here would need to be made, as well as their potential relative impact on environment and health.

In the case of lead glass – it has been noted that it is difficult to find one single alternative that will fully achieve all the properties provided by the introduction of lead (e.g. high refractive index, high dispersion without colouring the glass, economic melting temperatures, long working temperature range suitable for the traditional hand-working methods and high density) with comparable economic costs (Hynes and Jonson, 1997). For example, bismuth (present in the glass as Bi_2O_3) gives similar properties but is not as readily available and is less economically feasible (Hynes and Jonson, 1997). However, other unleaded formulations that are used include combinations of the modifiers (e.g. CaO, MgO, SrO and ZnO) which can result in glasses having properties similar to those of lead crystal (Hynes and Jonson, 1997).

From the above discussion, it can be inferred (although this is not fully clear) that use of cadmium and lead in ceramic and vitreous food contact materials would be difficult to justify in terms of a derogation using the essential use concept. In terms of demonstrating necessity/criticality, it is difficult to envisage the rationale for a derogation other than on the basis of cultural heritage and that aspect is also not fully clear. In terms of lack of alternatives, while alternatives are available, their 'acceptable' level of performance, and what level of performance loss could be acceptable to users, would need to be determined.

It should be noted that the assessment under the essential use concept may not take into account wider socio-economic factors related to this use – e.g. employment, knock-on effects on production for specific uses (e.g. tableware production) in Europe and impacts, for example of wider EU business and competitiveness. This is dependent on the policy options selected when implementing the concept (as detailed in Pact C of this report).

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		It is also indicated from the Commission's initiative[31] that other means of regulation could be applied to mitigate the negative aspects of reducing migration limits on industry – e.g. related to labelling, documentation, quality control, manufacturing instructions, and resulting testing exemptions; longer transition periods in case of specific needs requiring major investments.
	Challenges	Key challenges envisaged for applying the essential use concept in this case: ● The recommendations for defining the elements of 'criticality' in the horizontal criteria elaborated in this report (see Section 3 of Part B in this report) consider links to cultural heritage. They are important for providing predictability and clarity to potential applicants for derogation to anticipate whether their uses could fulfil these criteria. However, it is noted, on the basis of industry association comments, that a clear definition of what 'traditional, artisanal and culturally valuable products' would be required in the ongoing FCM legislation revision to inform migration limit revision – so this does not represent a major difference between the two scenarios[32]. ● Furthermore, this study has concluded that detailing a rigid definition for 'cultural heritage' is very challenging. While a number of existing definitions or descriptions exist, this study has not identified a set definition that would be fully compatible for the essential use concept. For example, it is not immediately clear if the artisanal use of cadmium/lead covered here for ceramic materials would fall into exiting definitions (e.g. by the UN). In practice, it has been suggested that a decision on derogations defending that a use is "critical for the functioning of society" on the basis of 'cultural heritage' aspects would potentially need to be supported through public/stakeholder inputs (e.g. through public consultation) and would ultimately be a political decision rather than a simple assessment against a set criteria. If additional consultation and/or data gathering would be carried out specifically with these aspects in mind, this would potentially result in additional time/administrative burden to the process and would also be challenging to incorporate the views of minority groups (e.g. the micro/artisanal users as are impacted in this case).

[31] European Commission. Initiative on ceramic and vitreous FCMs. Retrieved 2022-11-24 at: https://ec.europa.eu/food/safety/chemical-safety/food-contact-materials/policy-initiatives/initiative-ceramic-and-vitreous-fcms_de#:~:text=Initiative%20on%20ceramic%20and%20vitreous%20FCMs%20New%20initiative,nickel%20from%20ceramic%20and%20vitreous%20food%20contact%20materials.

[32] In this case the two 'scenarios' are i) the 'existing' situation with the Commission assessing the options for implementing stricter migration limits for cadmium and lead in ceramic and vitreous FCMs, and ii) the use of lead and cadmium being restricted and derogations being assessed on the basis of the 'essential use concept'.

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Potential impact of the ESU in this case	**Administrative burden**	Under the 'current' situation, considering setting stricter migration limits for cadmium and lead: As noted above, a key area of 'burden' for industry in terms of potential stricter migration limits concerns the testing requirements. Previous stocktaking discussions with the Member States and industry confirmed the potential significant burden of substantial lowering or introduction of new limits to heavy metals for certain business operators, in particular traditional and artisanal producers, which are mostly small and micro enterprises (European Commission, 2019). For these producers it appears difficult to apply more modern production techniques, as the value of their products derives directly from the use of traditional techniques and the relative cost for testing of small artisanal batches would likely represent a significant additional burden (European Commission, 2019). One option being considered by the Commission in the existing inception impact assessment is possible testing exemptions to reduce this burden (European Commission, 2019). Should the essential use concept be applied in this particular case in FCM legislation, several additional considerations may play a role: ● The need to develop a specific guidance for industry, tailored to this sector and use to ensure sufficient understanding for smaller businesses. ● Consideration whether it would be for individual applicants (in this case micro-businesses) to apply for a derogation (burden of proof on companies) and provide the necessary information (as well as the burden on authorities/Commission to assess these), rather than a simple entry to the legislation requiring compliance of all users with the same migration limits (burden of proof on authorities. Furthermore, if derogations are granted for this use on the basis of essential use (which is uncertain, based on the discussion above), it is possible that additional risk management measures would need to be applied to mitigate the continued risks. This could, for example involve labelling, quality control, but would also potentially involve application of a migration limit value for that substance. Therefore, even if exemptions from strict limits were in put in place, this would not in practice be less burdensome than the changes to the migration limits currently being considered by the (European Commission, 2019). Overall, in terms of administrative burden, it is difficult to envisage how the essential use concept would be less burdensome to key actors – e.g. industry, authorities, the Commission in this particular case.
	Timing of procedure	As discussed above, the setting of stricter migration limits for lead and cadmium in this use has been suggested following the EFSA (2009) and EFSA (2010) opinion documents However, stricter limits have not been

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implemented in the interceding time. This is currently the subject to work by the Commission to assess the potential impacts.

The issue of impact on smaller artisanal businesses, as well as issues around ensuring test methods that are workable and feasible for all manufacturers (as discussed above) and achievability of mitigation measures, has resulted in a relatively 'slow' process of revising the migration limits.

Under the essential use concept, with well-defined horizontal criteria in place (see Section 3 in Part B of this report), including clearly defined elements for demonstrating 'necessity/criticality', for example on aspects relating to cultural heritage, it can be expected that a restriction would be applied in a relatively strict and focussed way, and it could be envisaged this would have taken substantially less time to apply and achieve greater elimination of cadmium and lead.

Simplification of the regulatory procedures

It is difficult to compare the two situations[33] in terms of regulatory efficiency.

As discussed above, the potential revision to migration limits, and the measures to mitigate the impact of those migration limits on industry is currently subject to impact assessment work (European Commission, 2019). A range of different outcomes has been presented in the inception impact assessment. It is expected that, if stricter migration limits are applied, this will be accompanied by additional risk management measures, and will also likely involve testing to demonstrate compliance.

Therefore, in this respect, the application of the 'essential use' concept to this case could be seen as being a less simplified process than in the current situation. However, the essential use concept could potentially have led to the relatively early identification of 'non-essential' uses, where restriction of uses for lead and cadmium could have been enforced earlier based on their hazardous properties and the aim to eliminate such substances that are of most concern, according to the CSS.

It is envisaged that the implementation of the essential use concept could be included as part of the wider revision to FCM legislation for substances of most concern and would require substantial changes to the legal text. This would, in practice, represent a more complex means of regulating these chemical substances, as it would have

[33] In this case the two 'scenarios' are i) the 'existing' situation with the Commission assessing the options for implementing stricter migration limits for cadmium and lead in ceramic and vitreous FCMs, and ii) the use of lead and cadmium being restricted and derogations being assessed on the basis of the 'essential use concept'.

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		required specific assessments to determine the 'criticality' of lead and cadmium for specific uses/functions. As discussed in a number of case studies, depending on how disaggregated these uses/functions are in the application for derogation (i.e. how many specific uses/functions a single supplication covers), the more or less complex this process will be.
	Predictability	In both cases, predictability will be highly dependent on clear guidance to fully understand the process and requirements for complying with the regulation. While the compliance with migration limits is a relatively familiar concept for industry, it is noted (from the discussion above) that the present issue is that smaller business may not feel able or be willing to comply in practice. For example, for the revision of migration limits, industry has already (through the associated consultation) requested clarity on the definition of possible 'cultural/heritage' derogations, and specifics on which types of products would be covered. Similar detailed guidance (both horizonal and legislation-specific) would be needed if the essential use concept was to be applied. Given the small/micro scale of the artisanal business involved, it could be envisaged that tailored/targeted guidance and support may be needed for this specific case. Overall, it is difficult to compare the overall level of predictability between the existing scenario under the FCM legislation and the essential use concept. However, since the FCM legislation is currently being revised, there is the possibility that the essential use concept could be adopted as the basis for granting derogations from restrictions with horizontal guidance used to improve the predictability. However, it is noted that the consideration of the revised FCM legislation is not the subject of this case study.
	SMEs	The case study is particularly focussed on the use of cadmium and lead by micro/individual scale companies that will likely find it difficult to comply with strict migration limits due to the testing burden. It could be considered that these manufacturers would be able to meet the limits but would lack information from suppliers and the technical resources or funds to demonstrate compliance. Regardless of the scenario, it is expected support to smaller business would be needed, i) to support implementation and compliance, ii) to mitigate any disproportionate impacts e.g. in terms of costs, admin burden.

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	Sector-specific	It is noted that lead oxides are used as an intermediate for the chemical synthesis of Lead Crystal Glass, which is required under EU legislation[34]. The amount of lead has to be at minimum of 24% expressed as PbO for the glass to be called "crystal glass". This adds further difficulty in setting appropriate migration limits for lead in this specific sector who wish to continue to market or promote the FCM with this designation.
	Geographic	Expected to be implemented at Union-level. While in this study, it has not been identified if there are any specific Member States or areas are particularly more 'impacted' in this case, it is understood that there are certain MSs with a significant representation of artisanal ceramic producers.
Existing gaps in knowledge	• A key area of uncertainty impacting this case, is the lack of clarity regarding the definition of 'cultural heritage' in the context of both potential exemptions from migration limits, and the elements defined in the horizontal essential use criteria. • It is noted that the Commission has contracted a study to assess the efficiency, feasibility and acceptability of the measures to mitigate the impact of the migration limits, but this has not been published yet. • The specific definition of 'acceptable' alternatives is also important to clarify in this respect. This is applicable to all case studies considering the essential use concept but highlighted here in relation to chemicals in FCM. • The impact assessment work for the revisions to cadmium and lead migration limits is ongoing.	
Key lessons learned	• Based on the information presented in this case study, it is uncertain if the uses for cadmium or lead discussed here (i.e. in ceramic and glass food contact materials) would be considered 'essential' is this context. This is clearly not a clear-cut case so the assessment of a potential derogation for these uses on the basis of 'criticality' due to cultural heritage could be quite complex, time-consuming and burdensome to industry and authorities,. Even if certain uses were determined to be 'critical' on that basis, the essential use assessment would also consider the lack of alternatives, i,e., only those uses considered critical for the functioning of society without alternatives might qualify as 'essential'. • Detailing a rigid definition for what constitutes a use that is 'critical for the functioning of society' on the basis of cultural heritage is very challenging, and ultimately is a case where the decision would likely be almost entirely political decisions, compared to other cases where a more objective judgement can be made (e.g. in relation to standards or performance level). In practice, this	

[34] Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass.

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	may need to be supported by additional or more extensive or targeted public/stakeholder inputs. This could make the assessment process for a case like this one more time-consuming, burdensome and controversial.
References	EFSA (2009). Cadmium in food - Scientific opinion of the Panel on Contaminants in the Food Chain. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/980 EFSA (2010). Scientific Opinion on Lead in Food. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/1570 European Commission (2019). Inception impact assessment - Ares(2019)3505623. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2074-Food-safety-heavy-metals-in-ceramic-glass-and-enameled-table-and-kitchenware_en Hynes, M.J. and Jonson, B. (1997). Lead, glass and the environment, Chemical Society Reviews, http://www.theglassmakers.co.uk/pdffiles/hynesandjonson.pdf. JRC (2016). Testing approaches for the release of metals from ceramic articles - In support of the revision of the Ceramic Directive 84/500/EEC, https://op.europa.eu/en/publication-detail/-/publication/48e11380-d316-11e6-ad7c-01aa75ed71a1/language-en. Lehman, R. L. (2002). Lead Glazes for Ceramic Foodware, A publication of the International Lead Management Center: https://studylib.net/doc/18053508/lead-glazes-for-ceramic-foodware. Turner, A. (2019). Cadmium pigments in consumer products and their health risks, Science of the Total Environment, 20 (657):1409-1418. Doi: 10.1016/j.scitotenv.2018.12.096.

4. Lead in alloys under the Restriction of Hazardous Substances (RoHS) Directive

Case study name	**Exemptions under Directive 2011/65/EU on the restriction of hazardous substances in the electrical and electronic equipment (RoHS): A case study to lead in alloys, entries 6(a), 6(b) and 6(c) of 2011/65/EU An. III**
Introduction	Directive 2011/65/EU on the Restriction of Hazardous Substances (RoHS)[35] covers electrical and electronic equipment (EEE) and lays down restrictions for use of certain hazardous substances. One substance covered under the Directive is the chemical element lead (EC 231-100-4, CAS 7439-92-1). The total amount of lead (in different compounds) should not exceed 0.1% (w/w) in weight in homogenous material. However, some uses require a higher lead content to deliver the desired functionality. Hence, time-limited exemptions for a variety of applications of lead have been granted, allowing the use a higher lead content. These are listed in Annex III and Annex IV. These exemptions are regularly reviewed. This case study focusses on three exemptions granted for the use of lead in alloys for electrical and electronic equipment (EEE). These exemptions are the use of lead as an alloying element in steel, aluminium, and copper, granted for different reasons, including lead being purposefully added for machining purposes, unavoidable as impurity from secondary raw material and in galvanizing metals. The case study considers the process for assessing the application for a RoHS exemption and compares this to the situation that could occur if the essential use concept were applied to assess the exemption.
Research questions for case study	**Overall objective** – To assess how the essential use concept would have been implemented in this situation, if applied already, and investigate how it could have impacted this case of restriction/authorisation e.g., improved the effectiveness and efficiency of the process, the level of protection for health/environment, legal certainty, predictability, incentives to substitution, etc. The main objective of this task is to help elaborate the horizontal concept in Task 3. Main high-level questions: ● How could the main elements of the essential use concept (necessity/criticality/lack of alternatives) have been assessed in this specific case to inform the decision? ● What are the key practical challenges in applying the essential use concept to this particular case?

[35] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (“RoHS”) and associated delegated acts concerning the exemption of lead in alloys.

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	● What would be the impacts if the essential use concept were applied in this case – health/environment, economic, societal? ● What key lessons can we draw from this case study for implementing the essential use concept?	
Information sources and line of evidence	**Literature review**	Key sources of data are the legal text, applications for exemptions, published decisions of the European Commission, the ECHA documents and studies by the European Commission.
	Consultation	● Discussion with key Commission staff (from DG ENV). ● Inputs from stakeholders [confidential] during stakeholder interviews from person involved in the preparation of the previous assessment reports; and industry stakeholders gave input in oral and written form.
	Other Sources	The results from the stakeholder workshop on the concept of "essential uses"[36], especially the Break-out group on RoHS, were given consideration.
Background context	**Legislation**	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment lays down restrictions for certain hazardous substances, one of which is lead. Lead was a substance included in RoHS when the first version of the legislation came into force in 2003 as directive 2002/95/EC. Since then, RoHS has evolved and seen major changes through the reworking of the Directive in 2011 (2011/65/EU) and 2015 (2015/863). Furthermore, the exemptions included for lead underwent a development, mainly through the process of extending exemptions. During these renewal processes, the exemptions were consecutively broken down from a broad range to more specific uses. However, this added granularity resulted in an increasing number of individual exemptions and therefore increasing effort. At this point (May 2022), there are 35 highly specific entries in the exemption list (Annex III) concerning lead, a tenfold increase compared to the first version of RoHS. The newest study concerning the extension of the exemptions 6(a) to (c) concerning lead in steel, aluminium and copper alloys dated 02/2022, recommending a further increase in specificity. The RoHS regulation itself is currently being reviewed, with the public consultation open from 10/03/22 to 02/06/22.

[36] European Commission (2022). Stakeholder workshop on the concept of 'Essential uses'. 3 March 2022. Workshop report and background documents are available here: https://environment.ec.europa.eu/events/stakeholder-workshop-concept-essential-uses-2022-03-03_en.

Case study name	Exemptions under Directive 2011/65/EU on the restriction of hazardous substances in the electrical and electronic equipment (RoHS): A case study to lead in alloys, entries 6(a), 6(b) and 6(c) of 2011/65/EU An. III	
	On substance (and its alternatives)	Lead is a toxic heavy metal regulated across many different legislation, yet is still found in many products, from solder pastes in electronic devices to lead sinkers for fishing. Under REACH, lead and some of its salts are the specific subject of several entries in the restriction list (Annex XVII entries 16, 17, 63)37. These have to be taken into account, as RoHS exemptions need to be within the boundaries set by the REACH restriction. Exemptions granted under RoHS must not weaken the protection level provided by REACH (2011/65/EU Art. 5 (1) a) to ensure coherence between the legislations. Lead is a CMR substance and as such would likely constitute a 'most harmful' substance in the context of the essential use project.
	On use/function	There are two main reasons why lead is incorporated in steel, aluminium and copper alloys: Firstly, lead is used in alloys to provide desirable properties to the material. ● In steel, it may be intentionally added to enhance the machinability[38] through its lubrication effect and prevent cracks in the material acting as a chip breaker. Unintentional incorporation may stem from lead in zinc which is used in galvanisation processes. ● In aluminium, the reasons for lead incorporation are similar to steel: It may be added to enhance the machinability through its lubrication effect and prevent cracks in the material acting as a chip breaker, or unintentionally from the use of secondary raw materials, where e.g., aluminium may be recycled from lead-bearing aluminium scraps, ● In copper, the exemption is only for the intentional addition of lead to enhance the machinability of the copper through its lubrication effect and prevent cracks in the material acting as a chip breaker For the different alloys, alternative materials are known which give the final materials some of the desired properties that lead provides, but it is always a trade-off. In some uses the possible alternatives currently lack reliability and also broad applicability. Secondly, lead may also be present as an impurity due to its presence in scrap metal used as a secondary raw material, either in the recycled base metal itself (aluminium) or in metal used for galvanisation (zinc for steel galvanisation).

[37] Other lead compounds, which are not explicitly mentioned in Annex XVII not also relevant here, e.g., entry 19, entry 28 and 30, or entry 72.
[38] The ease with which the material is machined (i.e. processed or cut) in terms of specific energy, specific horsepower, or shear stress.

Case study name	Exemptions under Directive 2011/65/EU on the restriction of hazardous substances in the electrical and electronic equipment (RoHS): A case study to lead in alloys, entries 6(a), 6(b) and 6(c) of 2011/65/EU An. III	
		In principle, lead can be substituted where it is added intentionally by using other additives / alloying elements (e.g., bismuth or silver) to achieve some of the desired properties of the material, but usually it has some drawbacks. However, there is a consideration that there is currently no substance that would allow for a one-to-one substitution of lead to achieve the same function across all applications. For example, lead cannot easily be substituted, as the mechanical stability and lifetime of the final product could be impaired to an extent leading to a loss of performance that is not 'acceptable'. Furthermore, when applying alternatives, there can be safety concerns regarding the potential hazardous properties of the alternative also (regrettable substitution). Therefore, the availability of the alternatives to lead in these uses cannot be ensured for the time being, meaning market-readiness / capacity is not assured. If lead is present as an impurity, it may be avoided via further purification steps of the raw material, from which it stems, or using different raw materials. Purification is technically possible, but the removal of the lead to such an extent as to stay under the defined threshold is costly, potentially making the decontaminated the material unaffordable. Abandoning secondary raw materials would lead to increased costs and also goes against the idea of a "circular economy", where use of secondary materials from recycling processes is encouraged, while placing the same requirements on the content of chemicals for virgin as well as to recycled materials
	On the current situation	The rules for exemptions under RoHS: RoHS provides criteria for exemptions from the restrictions in Article 5, which states that materials should be included under an exemption when: their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable, the reliability of substitutes is not ensured, the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. Furthermore, reference to the REACH regulation is made, so that exemptions granted must "not weaken the environmental and health protection afforded by REACH (Regulation (EC) 1907/2006)" Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions take into account the availability of substitutes and the socioeconomic impact of substitution. Decisions on the duration of any exemptions take into account any potential adverse impacts on innovation. Lifecycle thinking on the overall impacts of the exemption also apply, where relevant.

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The requests for renewal of the exemptions 6(a) to (c) have been evaluated together in accordance with Article 5(7) of the RoHS Directive. The evaluation report has been published (Oeko-Institut, 2022).

The current exemptions in Annex III concerning lead in alloys allow:

- lead as an alloying element in steel for machining purposes and in galvanised steel, with different thresholds and expiry dates set for different category applications.
- lead as an alloying element in aluminium for different category applications, set with a threshold of 0.4 % but differing expiry dates, and also when it is added for machining purposes with up to 0.4 % and for some categories.
- lead in aluminium (0.4 %) which stems from lead-bearing aluminium scrap recycling.
- lead as an alloying element in copper up to 4 %, with different expiry dates in applications of different categories.

Further exemptions are listed in Annex IV for highly specialized devices and applications, where the reliability and special properties that lead grants to the respective alloys are considered necessary. These specific applications are not part of the case study presented here.

Exemptions in RoHS are generally provided with an expiry date. Renewal is possible upon application by stakeholders 18 months before the expiry date and thorough assessment whether the conditions for granting an exemption as laid out in the directive are still applicable. The assessment is based on information delivered by the stakeholders and is performed by external contractors by request of the Commission. Concerning the exemptions 6(a)-(c) about lead in alloys, the last such assessment report was published in February 2022.

The extension of the existing exemption was evaluated, recommending that an extension should be granted for most exemptions. The requested exemptions as proposed by the stakeholders were altered in structure, but to a large extent accepted. However, the expiry dates proposed for the different applications display a large variety (from expiry after 12 months of the adoption to several years). The exemptions for which 12-18 months is proposed are not granted. The time between 12-18 months is the transposition period (Art.6(6)), which should give stakeholder time to adapt to those changes. Exemptions which are granted are mostly granted 2 years up to the maximum validity periods, and industry can apply again for renewal.

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		This reflects the anticipated technical progress, which is expected to make the exemptions obsolete at a future point in time and also encourages the stakeholders to search for new, innovative alternatives or further develop existing ones, which are currently not considered "suitable" (e.g., because they are not widely available). For example, in the case of exemption 6(b)-II, it was said that this exemption is no more necessary and only for gas valves a specific exemption should be granted. That means, 6(b)-II will be revoked on ground of Art.5(1)(b). The intentional use of lead for machining purposes will be limited in the future. Existing exemptions remain valid until a decision on the renewal application is taken by the Commission (either to retain the exemption or not to prolong the exemption any-longer). This means, those requested exemptions will remain valid after the formal expiry date is passed, until there is no decision. This was and still is the case for those exemptions 6(a)-6(c). The evaluation of applications for exemptions relies on the information provided by the applicant and stakeholders through both, open and targeted stakeholder consultations. As the process progresses, the exemptions tend to narrow in scope with each round of the granting procedure. Additionally, the number of stakeholders involved also diminishes, hence only a few responses are received in later rounds (sometimes only 1 or 2). The number of stakeholders that wants to get involved in the process is also lowered by the effort needed to participate in the process, possibly discouraging SME engagement. Overall, the assessment in some cases may only rely on little information, which is technically very specific and sometimes conflicting statements may also be made by different actors. This introduces some uncertainty about completeness and correctness of the information assessed and also contributes to the prolongation of the process.
Application of Essential Use Concept Criteria	**Feasibility**	The three criteria proposed for the essential use concept, necessity for health or safety, criticality for the functioning of society and lack oft of alternatives, correspond to some extent with the three criteria assessed under the current process, where exemptions for application of the restricted substances should be granted if: their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable, the reliability of substitutes is not ensured, the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. *Assessment of alternatives*

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Starting with the most obvious correlation, consideration is already given to the question whether there are reliable substitutes available. Under the essential use concept this would also be assessed, however precisely how this would be operationalised in specific pieces of legislation (like RoHS) would need to be closely considered, for example to assess whether legislation specific guidance would be needed for the essential use concept.

For the three examples in question, the assessment under the current regime is exemplarily described in detail for steel.

Lead as an alloying element in steel for machining purposes and in galvanised steel containing up to 0.35 (w/w) lead and in batch hot dip galvanised steel components containing up to 0.2 % (w/w) lead:

Lead enhances the machinability of steel parts, as it provides a lubricating effect, and also enhances stability and longevity of tools, because it acts as a chip breaker, hence prevents the spreading of cracks in the final product. Its addition makes steel more costly, and it is therefore only used where a significant improvement to the properties of steel is required. Bismuth and Calcium may be used as a substitute to achieve a comparable effect regarding the machinability of steel. However, the use of bismuth is considered very costly and uneconomic, and also leads to performance drops of the respective steel alloy under hot conditions. Hence, it was not considered a suitable alternative. Calcium, while being less costly than bismuth, also leads to a similar drop in performance.

Lead may also come to be an alloying element in steel, where zinc galvanization techniques are used. It may be present as an impurity in the secondary raw material used in such processes or is intentionally added in some special applications to improve the properties of the galvanisation material (i.e. increases fluidity, so that even products with difficult geometry and small crevices can be galvanized). In the first case, the assessment of alternatives compares the use of virgin material or additionally purified secondary raw material to the use of secondary raw material.

Primary source material would in general not contain lead, which is incorporated into the secondary source material as impurity from solders, etc., but not recycling zinc would go against the aim for a circular economy and generate unnecessary waste. Avoiding lead where it is unintentionally added was deemed impractical. For the few special applications, where lead is added to improve the properties, there was no suitable alternative found that would deliver the same benign effect on fluidity and allow the galvanization of complex geometries.

Overall, the assessment of alternatives performed under the current regime takes into account technical, environmental and socio-economic aspects. The arguments brought forward for lead in steel, e.g., alternatives lacking technical feasibility, because no other material delivers the same, required properties, or them being

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uneconomic because re-use cycles would be hampered, are similar in the cases of lead as alloying element in copper and in aluminium.

Under an essential use concept, the socio-economic aspect is currently not considered, so that the outcome of the assessment of alternatives is likely to be different in the case where lead is an impurity in secondary raw materials, as the simple technical solution, using virgin material, is technically possible. For the cases where lead is intentionally added, the outcome would likely be the same, as the use of lead is essential to achieve the observed combination of desired properties and no suitable alternatives are available for all applications. However, it is noted that for lead in aluminium for machining purposes a limitation is proposed, which will reduce intentionally added lead in aluminium.

Necessary for health/safety and critical for the functioning of society:

Regarding the other two criteria, the proposed essential use concept distinguishes itself from the current system. While the essential use concept addresses the more fundamental question, whether the use of the substance is necessary for health or safety or critical for the functioning of society, the current criteria under RoHS are based on a comparison of benefit (e.g. for health) and negative impacts (health risk).

For example, applying the essential use concept could potentially narrow down the number of applications for derogations (and the number granted) as the risk / benefit analysis currently in effect does not ask whether the use of the substance is critical for society, but only if the use outweighs the risks. However, until specific criteria and additional guidance on the essential use concept would be defined, it is not certain if the relative number of applications or derogations would be different. Currently, “Criticality for the functioning of society or “necessity for health and safety” in the sense of the concept are not the main arguments for granting the respective exemptions in RoHS for lead in alloys, but rather the technical feasibility and availability of alternatives.

In case of the exemptions 6(a), 6(b) and 6(c) recommended in the most recent assessment (Oeko-Institut, 2022), the exemption is also made to facilitate the use of recycling material, which is due to the risk/benefit analysis, and also gives consideration towards the aims of a circular economy. Under the essential use concept, this exemption also might presumably be granted. Although this use is not necessary for health or safety, the question would be whether it is critical for the functioning of society as metal is a finite resource and not allowing the recycling might make such a material unavailable in the future. In making such a political judgment, the aims and objectives of circular economy would need to be considered, including the question under what conditions and with what quality requirements the recycling should be.

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		Regarding the cases where lead is intentionally added, the discussion of necessity/criticality will be exemplary shown for the example of lead as an alloying element in steel. First, machining steel can be identified as 'critical for the functioning of society' in many cases. For example (with reference to Section 3 of Part B in this report) these uses are likely to meet the criterion by falling under the element of resources or services critical to society (e.g. in infrastructure). It may be more difficult to demonstrate that use of lead is 'necessary for health or safety', however it is noted that only one of the two components of this first part of the essential use criteria ('criticality' or 'necessity'), would need to be met.
	Challenges	The key challenge under the current regime but would also impact the application of the essential use concept, is the high number of exemptions concerning a varied set of highly specialised technical uses of the regulated substance, the analysis of which requires key technological expertise, with sufficient staff resource working on the assessment to ensure timely completion of the exemption requests. The process requires all stakeholder to invest significant resources (time and personnel) and still results in a long duration of the process (up to 20 months). A challenge in implementing the essential use concept (as already discussed in relation to REACH-related case studies discussed above) is achieving appropriate balance in the 'granularity' of how the essential use concept is applied – i.e. a balance between strict criteria and a manageable process for industry/authorities to operate. On the side of the Commission and the consultants assessing the applications, gathering all the necessary information and judging its completeness and correctness can be difficult. Particularly when only few stakeholders are available and willing to contribute to the process. This means, that decisions may need to be taken on the basis of limited data, with higher uncertainty. A key consideration will therefore be the relative difference in the information requirements and complexity of applying for derogations between the 'existing' situation and the corresponding process under the essential use concept. For stakeholders, the challenge is the regulatory uncertainty faced during a prolonged decision process, and the effects of highly segmented exemptions leaving only few and very specialised uses available. When only niche uses are allowed, the production as a whole might become unattractive, leading to loss of production capacity in Europe for substances that are needed in applications considered "essential". However, the Commission may take these points into account during the risk / benefit analysis, as evidenced by increasing number of specific exemptions instead of revoking general exemptions totally. This would not be possible under the proposed hazard-based approach of the essential use concept. Currently Article 5(1) states, that the decisions on exemptions "shall take into account the availability of substitutes and the socioeconomic impact of substitution". As the socioeconomic aspects are, in the present stage, not considered in the essential use concept, this procedure would have to be amended, with a significant impact on running exemptions, leading to a transitional period with great variability in the process of assessing exemptions

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		(new exemptions would be assessed with the essential use concept and the older exemptions already in the assessment phase would be assessed with the old procedure). Additionally, the duration of an exemption is linked to the "potential adverse impacts on innovation", which could however be integrated into the process and the essential use concept. Therefore, a challenge for the implementation of the essential use concept is developing a criterion for the assessment of alternatives that is consistent/compatible with this existing process. Regarding the lead in alloys exemption specifically, another challenge arises from the fact that they cover both intentional and unintentional addition (impurities) of lead, the latter of which arises from the use of secondary raw material. This exemption is granted as a balancing act, weighing the harm of incorporating lead in exempted cases in new products against the benefits of using recycled material.
Potential impact of the essential use concept in this case	**Administrative burden**	In the current process, the Commission foresees the evaluation of the requests (for derogation) in a close cooperation with external experts under close cooperation with the Commission. The evaluation includes, health, environmental and socioeconomic aspects and impacts as well as possible alternatives and the status of the substitution of the substance. For competent authorities, the effort required to assess exemption requests, if the essential use concept would replace the current system, would shift its focus, but not necessarily lower the expense. As new stricter criteria, such as necessity for health or criticality for the functioning of society would be assessed in addition to technical feasibility it would be more difficult to prove this for the manufacturer, and probably more information would also be needed from the users. The response to stakeholder consultations is already low with the current RoHS approach, and it cannot be assumed that this would change with different criteria. Hence, it may be more difficult to establish a solid foundation for decisions. For companies, the administrative burden would increase, as currently in many cases they can use their own data to show, that alternatives are not available and lay out that a substitution is not possible. However, under essential use criteria, they would also need to show the 'necessity for health and safety' or 'criticality for the functioning of society' of the use of the substance, which would likely require more information from different actors across different parts of the supply chain up to the end user. An essential use concept could, however, decrease the number of requested exemptions by helping to identify clearly 'non-essential' uses before going into in-depth analysis of the request. However, for cases in which the necessity and/or criticality is not directly clear, a detailed analysis similar to the current process would have to be performed, including an assessment of alternatives. For such cases, the reduction in the administrative burden is expected to be minimal.
	Timing of procedure	Currently a request for exemption is expected to take up to 20 months (10 months for the technical evaluation and 10 months for the decision of the Commission). For singular exemptions, this timeframe can be shortened to 12-15

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	months. The bottlenecks are the evaluation of requests as well as the decision process of the Commission. As the criticality/necessity of the use of the substances as well as its alternatives would have to be evaluated under an essential use concept, the implementation of such a concept is not expected to significantly shorten the required time to decide upon a request for exemption. As discussed above, in some cases, it may be possible to use the essential use criteria to help identify clearly non-essential uses. This may help to lower the number of requests to be evaluated and therefore reduce the overall burden, allowing prioritisation on the remaining exemptions, which may shorten the turnaround time for decisions. The recurring evaluation of a high number of exemptions was identified as a key driver for increasing the time required for the process. Different approaches to this issue exist which are being considered in the ongoing RoHS revision, one of them is being more flexible with the duration for exemptions, of which some can be foreseen to be required in the long term. However, under the essential use concept, some uses would be quickly identified as "non-essential", while for the others the decision process is expected to be in the range of the current timeframe.
Simplification of the regulatory procedures	The introduction of an essential use concept would shift the focus of the evaluation from environmental, health and socioeconomic aspects to the question whether a use is essential (in the end also encompassing the environmental and health aspects when setting conditions for allowing an essential use). This question can sometimes be answered quickly which would decrease the number of the exemption requests, however for the cases where the question cannot be easily answered a full analysis would still have to be performed. As such the essential use concept is not expected to significantly simplify the regulatory procedure.
Predictability	For some exemptions, the necessity/criticality of the use could be evident from the beginning, if potential applicants can refer to a clear fulfilment of all criteria, based on the detailed elements defined for the horizontal criteria, as outlined in Section 3 of Part B in this report, making it clear to the prospective applicants whether their request will be granted or not. For example, this is likely related to 'critical' resources or services (e.g. public infrastructure) where there clearly are not available alternatives. However, for the majority of cases the necessity/criticality cannot be quickly determined and requires an in-depth analysis. As the uses are oftentimes very specific it is difficult to predict the outcome of such an analysis. Thus, the outcome from the assessment based on the essential use concept is not necessarily more predictable than from the current process. Nevertheless, clearly defined criteria can create a more transparent and predictable process when deciding on exemption to be granted or not.

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	SMEs	The effort of applying for an exemption is often too big for singular SME, hence often associations take over the process, if at all. It is not expected that changing the criteria to essential use criteria alone would motivate more SME companies to involve in stakeholder consultations. A guidance document[39] has been created for the current exemption process, which informs about the administrative process and aspects to be considered (Oeko-Institut, 2012). It is recommended to create such a document for the application of the essential use concept in order to lessen the burden on industry when applying for an exemption. This can include aspects/evidence which need to be provided in order to prove that a use is 'essential', including data on alternatives and their applicability. Such a guidance is especially useful for SME as they often do not have the necessary resources to research the process and its requirements themselves.
	Sector-specific	Any company can apply for an exemption. .
	Geographic	As every exemption is valid for the whole EU and every company producing such parts may make use of it, it is not expected that the introduction of an essential use concept will be accompanied by geographical impacts.
Existing gaps in knowledge	• In general, the impacts of the essential use concept are difficult to predict in such specific applications as subject to this case study. Necessary information relevant to the concept would have to be provided by relevant stakeholders in order to perform a full assessment. • It would have to be assessed in each case how much loss of performance from choosing a different alternative is acceptable. Lead also prolongs the lifetime of certain products by preventing cracks from forming. The use of a substitute might shorten the lifetime of such a product and in return have a higher impact on the environment by needing a new product after a shorter amount of time.	
Key lessons learned	• The essential use concept can reduce the amount of requested and to be processed applications by excluding clearly non-essential applications or applications where alternatives are readily available. • The essential use concept should bring concrete elements/definition to clearly demonstrate which specific uses are considered 'essential' so that appropriate derogations are granted. This would increase the predictability and ease the administrative burden during the process as currently no such elements are defined. • The requests for exemption/the exemptions granted are currently getting more and more specific, which on one hand leads to production as a whole potentially becoming unattractive due to fragmentation; on the other hand it also highlights cases which	

[39] Öko-Institut e.V. (2012). Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU. 30 August 2012.

Case study name	**Exemptions under Directive 2011/65/EU on the restriction of hazardous substances in the electrical and electronic equipment (RoHS): A case study to lead in alloys, entries 6(a), 6(b) and 6(c) of 2011/65/EU An. III**
	cannot be substituted. Such cases can be taken as a starting point for the application of an essential use concept to further pressure for substitution in the remaining uses. • The separation of the use of a substance and the product the substance is used in is oftentimes difficult. Lead is often added as lubricant for the machinability of alloys, which in many products would probably not be seen as essential. However, in high performance steel construction for example, which needs a certain degree of flexibility, such a use could be seen as essential. The case-by-case assessment of the 'criticality' of this use according to the elements defined in Section 3 in Part B of this report also contained recommendations for this type of situation (see Section 3.4).
References	Oeko-Institut e.V. (2008). Study on Hazardous Substances in Electrical and Electronic Equipment, not regulated by the RoHS Directive. Oeko-Institut e.V. (2012). Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU, Available at: https://environment.ec.europa.eu/system/files/2021-01/Guidance_Document.pdf. Oeko-Institut e.V. (2022). Study to assess requests for a renewal of nine exemptions 6(a), 6(a)-I, 6(b), 6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I and 7(c)-II of Annex III of Directive 2011/65/EU. Available at: https://op.europa.eu/en/publication-detail/-/publication/c774eb67-7cc6-11ec-8c40-01aa75ed71a1/language-fr?msclkid=0cc99a8ccd2e11eca95a87fdd988e949.

5. Bis(2-ethylhexyl) phthalate (DEHP) in medical devices under the Restriction of Hazardous Substances (RoHS) Directive

Case study name	***Bis(2-ethylhexyl) phthalate (DEHP) in medical devices entries 45, 46 and 47 in Annex IV of RoHS***
Introduction	This case study focusses on the use of bis(2-ethylhexyl) phthalate (DEHP)40 in medical devices. DEHP is restricted in Directive 2011/65/EU on the restriction of hazardous substances in the electrical and electronic equipment (RoHS). For purposes of this case study, the focus has been on three specific exempted applications of the use of DEHP in medical devices (use in MRI coils, use in ion-selective detectors and use in spare parts) under RoHS. The case study considers the process for assessing the application for an RoHS exemption, and compares this to the situation that could occur if the essential use concept had been used to assess this use and the impacts arising from the application of the concept for this particular use in RoHS41.
Research questions for case study	Overall objective – To assess how the essential use concept would have been operationalised in this situation, if applied already, and investigate how it could have impacted this case of exemptions from restriction e.g. improved the effectiveness and efficiency of the process, the level of protection for health/environment, legal certainty, predictability, incentives to substitution, etc. The main objective of this task is to help elaborate the horizontal concept in Task 3. Main high-level questions: ● How could the main elements of the essential use concept (necessity/criticality/lack of alternatives) have been assessed in this specific case to inform the decision? ● What are the key practical challenges in applying the essential use concept to this particular case? ● What would be the impacts if the essential use concept were applied in this case – health/environment, economic, societal? ● Would have the outcome been different if the concept were applied?

[40] It is noted that butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) are also subject of the exemption 47 IV (spare parts), but this case study is focussed on DEHP only.

[41] It is noted to the reader that the REACH authorisation provisions applicable to the use of DEHP in medical devices have been modified by Regulation (EU) 2021/2045[41], which included the endocrine disrupting properties of DEHP for the environment in Annex XIV listing of REACH, making so uses of DEHP in medical devices subject to the authorisation requirement under REACH. This case study however does not cover REACH authorisation requirements.

Case study name	*Bis(2-ethylhexyl) phthalate (DEHP) in medical devices entries 45, 46 and 47 in Annex IV of RoHS*	
	• What key lessons can we draw from this case for implementing the essential use concept?	
Information sources and line of evidence	Literature review	Key sources of data are the legal text, applications for exemptions, published decisions of the European Commission, the ECHA documents and studies by the European Commission. See the full reference list below.
	Consultation	A Commission representative from DG ENV, two industry associations and a RoHS-consultant were interviewed.
	Other Sources	The discussions during the stakeholder workshop on the concept of "essential uses", especially the break-out group on RoHS, were also given consideration.[42]
Background context	Legislation	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment lays down restrictions for certain hazardous substances, one of which is DEHP. The DEHP content is restricted in Annex II to a maximum of 0.1% in homogeneous materials. However, some uses require a higher DEHP content to deliver the desired function. Hence, exemptions for a variety of applications of DEHP have been granted in order to be able to use a higher concentration. These are listed in Annex IV. The RoHS Directive itself is currently being reviewed, with the public consultation open from 10/03/22 to 02/06/22.
	On substance (and its alternatives)	The intrinsic properties of DEHP include toxicity for reproduction and endocrine disruption for both human health and the environment. To substitute DEHP in medical devices covered by the current RoHS exemptions, other phthalate plasticisers such as diethylhexyl terephthalate (DEHT), di-isononyl phthalate (DiNP), di-isodecyl phthalate (DiDP) and ditridecyl phthalate (DTP) may be used (COCIR, 2019). Also other non-phthalate plasticisers such as nitrophenyl octylether (NPOE), dioctyl sebacate (DOS) or dioctyl adipate (DOA) can be employed. Alternatively, the use of DEHP can be substituted by using a different polymer that does not require the use of plasticisers such as polyethylene, ethylene propylene rubber or ethylene-propylene diene rubber (COCIR, 2019).
	On use/function	DEHP is a manufactured chemical, belonging to the group of phthalate plasticisers, that is commonly added to plastics (mainly PVC) to make them flexible, albeit over time, it has been replaced in most applications. Of relevance for medical devices, DEHP can be found in printed circuit boards (PCBs); X-ray tubes (including PCBs, cables, housing); in plastic components in magnetic resonance imaging (MRI) detector coils; and transducers with

[42] European Commission (2022). Stakeholder workshop on the concept of 'Essential uses'. 3 March 2022.

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		associated cables (Oeko-Institut e.V., 2020). It is also used as a membrane solvent for the ion selective electrode (ISE) constituents that are used in point of care (PoC) analysers to measure the concentrations of analytes such as partial pressure of carbon dioxide (pCO_2), pH, concentration of sodium and potassium ions. In the three regarded exemptions DEHP fulfils different functions: ● In spare parts[43] and in MRI coils DEHP is added to provide flexibility to the plastic components. Especially in MRI coils DEHP is added to the cables of the receiver coils to plasticise them. These receivers are used multiple times a day on different body parts and as such the plastic in the cables needs to be flexible and not break over the lifetime of the product (COCIR, 2019). The uses in spare parts are of a more general nature; however, they also relate to the use as plasticiser in plastic parts such as cables insulation, O-rings and connectors. It is also used as an additive in rubber grommets that support cables (COCIR, 2018). ● In ion-selective detectors, DEHP is used as a membrane solvent for the ion selective electrode constituents. These are made of ~30w/w% PVC and 70w/w% DEHP, where the plasticiser must among other things be liquid over a wide range of temperatures, not induce phase separation and be compatible with, and solvate the other membrane components (PubChem, 2022).
	On the current situation	DEHP was added to Annex II of the RoHS Directive on 31.03.2015 with the restriction coming into force on 22.07.2021 which also includes the restriction of DEHP in medical devices, including in vitro medical devices[44]. In 2018 and 2019 the Commission received several requests in accordance with Article 5(3) of the RoHS Directive for the exemption of the use of DEHP in medical devices. Concretely, for the use in recovered spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of medical devices, the use in plastic

[43] According to RoHS Art. 3(27), 'spare part' means a separate part of the electrical and electronic equipment (EEE) that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part.
[44] Commission delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

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components in magnetic resonance imaging (MRI) detector coils and the use in ion selective electrodes for analysing human body fluids and/or in dialysis fluids were requested to be exempted[45] [46] [47].

The exemption for the use in spare parts was already granted, however it expired on 22.07.2021. The exemptions on the use in MRI coils and in ion selective electrodes have been newly requested.

The rules for exemptions under RoHS

RoHS provides criteria for exemptions from the restrictions in Article 5, which states that for the inclusion of a material and component of EEE for specific applications in the lists in Annexes III and IV any of the following conditions needs to be fulfilled:

- their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable,
- the reliability of substitutes is not ensured,
- the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Furthermore, reference to the REACH regulation is made, so that exemptions granted must “not weaken the environmental and health protection afforded by Regulation (EC) 1907/2006“.

Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution. Decisions on the duration of any exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant.

[45] Commission Delegated Directive (EU) 2021/1978 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices.
[46] Commission Delegated Directive (EU) 2021/1979 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils.
[47] Commission Delegated Directive (EU) 2021/1980 of 11 August 2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids.

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The requests have been evaluated together in Pack 17 which included stakeholder consultation in accordance with Article 5(7) of the RoHS Directive. The evaluation report has been published online.

Three exemptions were granted on 11.08.2021 with the following justifications:

- The use of DEHP in spare parts
  - "The evaluation of the exemption application concluded that the total negative environmental and health impacts of substituting refurbished parts containing DEHP […] with new substance-free refurbished parts are likely to outweigh the total environmental and health benefits."
- The use of DEHP in MRI detector coils
  - "The evaluation of the applications, which took into account the availability of technically practicable and reliable substitutes and the socioeconomic impact of substitution, concluded that no suitable alternatives to DEHP are sufficiently available on the market and that not granting the exemption is likely to result in total negative environmental, health and consumer safety impacts caused by substitution, which outweigh the benefits thereof."
- The use of DEHP in ion-selective electrodes
  - "The evaluation of the application concluded that alternatives to DEHP are currently not sufficiently reliable and that the substitution of DEHP in specific applications would result in negative environmental and health impacts that outweigh its benefits."

Exemptions in RoHS are generally provided with an expiry date. Renewal is possible upon application by stakeholders before the expiry date and thorough assessment of whether the conditions for granting an exemption as laid out in the directive are still applicable. As the expiry dates for the different applications of DEHP only expire in 2024 or 2028 no request for renewal has yet been made. The duration for the exemptions reflects the anticipated technical progress, which is expected to make the exemptions obsolete at some time and also encourages the stakeholders to actively search for suitable alternatives. The rules for the length of the exemption are described in Article 5(2) of the Directive.

As mentioned above, the evaluation of applications for exemptions relies on the information provided by the applicant and stakeholders through both open and targeted stakeholder consultations. Currently the exemption process takes about 12-20 months for each exemption depending on the complexity and number of applications. As the exemptions, with each round of granting procedure, tend to narrow down in scope, the number of stakeholders involved also diminishes, hence only few responses are received (sometimes only 1 or 2). The number of stakeholders wanting to contribute to the process is also lowered by the effort related to participating in the process,

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		possibly discouraging SMEs. Overall, the assessment in some cases may only rely on little information, which is technically very specific and sometimes conflicting statements may also be made by different actors. This introduces some uncertainty about completeness and correctness of the information assessed and also contributes to the prolongation of the process.
Application of Essential Use Concept Criteria	Feasibility	**Scope** ● DEHP is an SVHC due to reproductive toxicity and has also been identified as an endocrine disruptor, so as such would likely constitute one of the 'most harmful' substances in the context of the essential use concept. **Necessary for health/safety and critical for the functioning of society** ● Whether a use is 'necessary for health or safety' and 'critical for the functioning of society' is currently not explicitly considered in the RoHS Directive. ● Most of the 'risk/benefit' assessment currently carried out in this case would likely not be relevant in the context of demonstrating 'necessity' or 'criticality' and lack of alternatives, as defined under the essential use concept criteria (see Section 3 of Part B in this report). However, in the requests for exemption the quality of health care was used as an argument to continue the use of DEHP, as it provides the best results when compared to other alternatives. Under the essential use concept, this would involve adhering to the more specific essential use criteria for 'necessity' or 'criticality'. ● As the use of DEHP in these applications is linked to the quality of the provided health care it is likely that this use would be deemed necessary for health and safety. It was stated in the requests that without the use of DEHP the required performance of the relevant medical equipment cannot be achieved and as such the quality of health care would decrease. When considering what uses could be considered as 'essential' with reference to the horizontal essential use criteria (see Section 3 of Part B in this report), the following uses are expected to be relevant: ▸ In MRI coils DEHP fulfils the role of plasticiser in cables, mattresses, fixing belts and bushing components. These components need to be flexible as they are used multiple times a day, for different patients and in different positions. The used polymer should therefore not break under the stress. Some polymers require the use of plasticisers in order to achieve flexibility and such flexible polymers (with the polymer specific properties) are needed in society. As such the use as plasticiser of DEHP in MRI coils will likely be seen as necessary for health, safety or the critical functioning of society. This will likely also be the case for the use of DEHP as plasticiser in plastics spare parts for medical devices.

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- In ion-selective electrodes DEHP is used as a membrane solvent with typical application concentrations of 70% w/w. Such electrodes are highly specialised and can quickly determine the concentrations of certain ions in blood in less than 60 seconds. Obtaining quick results on blood analysis is crucial in certain cases and DEHP fulfils a function in providing such quick results. Thus, it can be argued that the use of DEHP is necessary for the availability of the product and as such for the critical functioning of society.

- Lastly, the aspect of 'essentiality' is mentioned in two of the requests for exemptions. For example, in the request for exemption for the use of DEHP in MRI coils it was noted that DEHP-free coils cannot be made that meet all essential [performance] criteria (under RoHS). For purposes of this case study, it is clarified that this is not referring to the 'essential use' criteria. It can be expected that the 'essential' performance criteria would be relevant in the assessment under the essential use concept as this would be indicative of both 'necessity/criticality' and what are available alternatives. .

- In the request for exemption for the use in ion-selective detectors the word essentiality was used (as is the case in many applications), stating that "DEHP is an essential component of medical IVD analysers for the measurement of specific substances in body fluids", as these need to provide results in under a minute and other substances "have been found to give less accurate and incorrect test results".

Alternatives assessment

- Alternatives are already considered in the request for exemption and during the subsequent evaluation by the Commission. As such it is likely that the assessment of alternatives is likely to be broadly similar under the essential use concept, however, in all three cases the assessment of alternatives considered aspects, highly specific to the respective field. This would likely be similar in the case of the essential use concept.

- The health aspects, especially in the case of exemptions for the medical industry, are hard to quantify as they also encompass health care aspects and not only the health impacts of the alternative.

- The decisions for the exemption of the use of DEHP in MRI coils and in ion-selective detectors were based on the lack of alternatives. The parts in such medical devices need to fulfil a very specific performance which cannot be achieved by many substances and substances with a lower performance can drastically diminish the output quality of the device.

  - The MRI technology detects protons in the body and generates an image from the received signals. It is thus sensitive to protons present in the coil materials or any other component that is close to the patient. The components are designed to minimise any effect on the image quality, which requires the polymers and additives to have weak proton signals. This is the case of the currently applied PVC and DEHP

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combination. In theory a different polymer, which does not require a plasticiser could be used and DEHP could be substituted for a different plasticiser, however, to date no suitable material has been found which produces the same image quality as the PVC and DEHP combination and also complies with other legislation that is applicable to medical devices. Under an essential use concept, it is likely that a similar conclusion will be drawn, due to the necessity of high performing medical equipment. In such a case a lower performance could have severe impacts on the quality of the provided health care.

  - In ion-selective detectors a substitution is technically possible, however, the process is quite lengthy and a switch to an alternative plasticiser is currently not possible. The alternative needs to fulfil several criteria (see section on use/function), and only a few selected plasticisers are possible candidates. In most cases their potentiometric drift (i.e., the intrinsic voltage change over time) was too great for it to be a drop-in alternative (i.e., an alternative which can be used as a direct substitute without having to change the process/product). The exemption was then granted on the basis that no drop-in alternative is currently available. It is likely that a similar decision would be made under an essential use concept as the use of other plasticisers could significantly lower the quality of the provided healthcare.

- For the use of DEHP in spare parts it was argued that the negative environmental and health impacts of substituting the use of DEHP will be greater than the total environmental and health benefits. Such an aspect is currently not directly considered in the essential use concept, however this can be partially covered by considerations of the acceptability of alternatives from the standpoint of environment and health.

General aspects

- Generally, the focus under the current RoHS exemption already includes environmental aspects and the scientific and technical practicability of the alternatives, however, it also includes socio-economic aspects, which are not envisioned in the essential use concept.
- After listing a substance in Annex II of the Directive (restriction) there typically is a transition period after which the restriction comes into force. Should a use falling under the essential use concept be restricted in the future, such a transition period can provide industry with enough time to assess whether that use could qualify as necessary for health and safety or critical for the functioning of society and whether alternatives are not available.

Challenges	The current challenges of RoHS exemption criteria are the high number of exemptions for a broad variety of specialised technical uses being requested and renewed. The criteria laid out in Article 5 of the RoHS-Directive are formulated in a very general way and do define precisely when an exemption should be granted. Rather, they rely

on a case-by-case assessment. This leads to difficulties in deciding whether or not to grant an exemption in some cases. This is further supported by the fact the exemption process is highly dependent on the available information and stakeholder input. The exemption can only be as specific as the supplied information allows it to be. This is often used by industry to achieve more general exemptions, however, the adequate analysis requires technological expertise in many levels and areas, with sufficient staff working on the assessment to ensure timely completion of the exemption requests.

With each revision cycle, the exemptions become more and more specific and more and more hazardous substance is avoided being placed on the market, however, more specific exemptions also highlight cases where the use of the substance cannot be substituted. Furthermore, gathering all the necessary information and judging its completeness and correctness can be difficult, when only few stakeholders are available and willing to contribute to the process. A challenge in implementing the essential use concept (as already discussed in relation to REACH-related case studies discussed above) is achieving appropriate balance in the 'granularity' of how the essential use concept is applied – i.e. a balance between a strict criteria and a manageable process for industry/authorities to operate.

For stakeholders, the challenge is the uncertainty faced during a prolonged decision process, and the effects of highly segmented exemptions leaving only few and very specialised uses available. When only niche uses are allowed, the production as a whole might become unattractive, leading to loss of production capacity in Europe for uses that are considered "essential".

Additionally, the RoHS-Directive would have to be amended to include the essential use concept and aspects of essentiality. Currently, Article 5(1) states, that the decisions on exemptions "shall take into account the availability of substitutes and the socioeconomic impact of substitution". As the socioeconomic aspects are currently not considered in the essential use concept, this procedure would have to be amended. Additionally, the duration of an exemption is linked to the "potential adverse impacts on innovation", which could however be integrated into the essential use process.

As the exemptions have become more and more specific over time the amount of substance used under the exemptions has become less and less. The exemption request for DEHP in ion selective membranes states that annually 2.2 kg of DEHP would be placed on the market across the whole EU. It is emphasised that the essential use concept will require still the minimisation of use and environmental releases of the most harmful chemicals, even where derogations based on necessity/criticality are permitted. It can therefore be expected that the trend noted above for DEHP under RoHS can be extended under the essential use concept.

The use as plasticiser would be labelled as not essential in many cases as many products do not need such a functionality or the functionality can be achieved by other means (different polymer/plasticiser/product shape). In this

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		context, it may not be so difficult to proof the lack of alternatives for the use of DEHP as a plasticiser in medical devices within the essential use concept, also considering the product in which it is used. A stakeholder from an EU institution commented that in addition to considering the product, the setting of use should be considered. For instance, the use of one of the most harmful chemicals in lamps with a high colour rendering index (CRI) (e.g., mercury has been exempted under RoHS for this use) might not be considered 'critical/necessary' when they are used in shops, but could be considered 'critical/necessary' when used in emergency units during hospital operations.
Potential impact of the ESU in this case	Administrative burden	In the current process, the Commission evaluates the requests in a close cooperation with external experts. The evaluation includes, health, environmental and socioeconomic aspects and impacts as well as possible alternatives and the status of the substitution of the substance. The highest burden stems from the high number of requested exemptions (around 60 currently in progress) and the available resources at the Commission to process these. For authorities, the effort required to assess exemption requests, if the essential use concept were to replace the current system, would shift its focus, but not necessarily lower the expense. As new criteria, such as 'necessity for health and safety' or 'criticality for the functioning of society' were assessed in addition to technical feasibility of alternatives it would be more difficult to prove this for the manufacturer, and probably more information also from the users would be needed. Hence, this would represent a stricter criterion to justify derogations from a restriction. The responses to stakeholder consultations are already low, and it cannot be assumed that this would change with different criteria. Hence, it may be more difficult to establish a solid foundation for decisions. For companies, the administrative burden would increase, as currently in many cases they can use their own data to show that alternatives are not available and set out why substitution is not possible. However, under essential use criteria, they would also need to demonstrate the use of the substance, is 'necessary/critical' which would likely require more information from the whole supply chain up to the end user. Furthermore, when looking for possible alternatives not only the technical feasibility but also the environmental and health impacts would have to be considered by industry in order to comply with the aspect of the essential use criteria on 'acceptability of alternatives from the perspective of environment and health'. An essential use concept could, however, decrease the number of requested exemptions by rejecting clearly non-essential uses before going into in-depth analysis of the request. For cases in which the necessity/criticality is not directly clear, a detailed analysis similar to the current process would, however, have to be performed, including an assessment of alternatives. For such cases, the reduction in the administrative burden is expected to be minimal.
	Timing of procedure	Currently a request for exemption is expected to take up to 20 months (10 months for the technical evaluation and 10 months for the decision of the Commission). For singular exemptions, this timeframe can be shortened to 12-15 months. The bottlenecks are the evaluation of requests as well as the decision process of the Commission. As the

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		criticality/necessity of the use of the substances as well as its alternatives would have to be evaluated under an essential use concept, the implementation of such a concept is not expected to significantly shorten the required time to decide upon a request for exemption. As discussed above, in some cases, it may be possible to use the essential use criteria to help identify clearly 'non-essential' uses. This may help to lower the number of requests to be evaluated and therefore reduce the overall burden, allowing prioritisation on the remaining exemptions, which may shorten the turnaround time for decisions. The recurring evaluation of a high number of exemptions was identified as a key driver for increasing the time required for the process. Different approaches to this issue exist which are being considered in the ongoing RoHS revision, one of them is being more flexible with the duration for exemptions, of which some can be foreseen to be required in the long term. However, under the essential use concept, some uses would be quickly identified as "non-essential", while for the others the decision process is expected to be in the range of the current timeframe.
	Simplification of the regulatory procedures	The introduction of an essential use concept would shift the focus of the evaluation from environmental, health and socioeconomic aspects to the question whether a use is essential (in the end also encompassing the environmental and health aspects when setting conditions for allowing an essential use). This question can sometimes be answered quickly which would decrease the number of the exemption requests, however for the cases where the question cannot be easily answered a full analysis would still have to be performed. As such the essential use concept is not expected to significantly simplify the regulatory procedure.
	Predictability	Depending on how clearly defined the essential use criteria are, for some exemptions the necessity/criticality of the use could be evident from the beginning making it clear to the applicant whether their request for will be granted or not. However, for the majority of cases the necessity/criticality cannot be quickly determined and requires an in-depth analysis. As the uses are often very specific it is difficult to predict the outcome of such an analysis. Clearly defined criteria can create a more transparent and predictable process when deciding on exemption to be granted or not. Currently the RoHS Directive allows the use of restricted substances for cables and spare parts for "EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned". It was stated by an industry representative that such an exemption should also be included in the essential use concept and even that spare parts as a group could be labelled as essential as they are necessary for repair and thus longevity of the products and only use minimal amounts of hazardous substances on an annual EU-wide basis. However, it is noted that the essential use concept is not applied at product level.

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	SMEs	The effort of applying for an exemption is often too big for singular SMEs, hence associations often take over the process, if at all. It is not expected that changing the criteria to essential use criteria alone would motivate more SMEs to involve in stakeholder consultations. A guidance document has been created for the current RoHS exemption process, which provides information on the administrative process and aspects to be considered. If implemented, creating such a document for the application of the essential use concept would help to lessen the burden on industry when applying for an exemption (Oeko-Institut e.V., 2012). This could include aspects/evidence which need to be provided in order to prove that a use is essential as well as data on alternatives and their applicability. As mentioned above a transition period after a restriction of a substance instead of the restriction coming into force immediately can be an efficient tool to ease the burden on industry. With a legal restriction (instead of a proposal for restriction) it is easier for companies to obtain information from the supply chain and as such it is easier to substitute the use of a substance. Furthermore, this would allow industry to start looking for alternatives for uses which have not yet been assessed early on. After the transition period a company would have a better understanding whether the use can be substituted or not and can then apply for a derogation under the essential use concept. Such a transition period is especially relevant for the medical sector due to the long design cycles.
	Sector-specific	Any company can apply for an exemption.
	Geographic	As every exemption is valid for the whole EU and every company producing such parts may make use of it is not expected that the introduction of an essential use concept would be accompanied by geographical impacts.
Existing gaps in knowledge	• In general, the impacts of the essential use concept are difficult to predict in such specific applications as subject to this case study. Necessary information relevant to the concept would have to be provided by relevant stakeholders in order to perform a full assessment. • It would have to be assessed in each case how much loss of performance from choosing a different alternative is acceptable. Lead also prolongs the lifetime of certain products by preventing cracks from forming. The use of a substitute might shorten the lifetime of such a product and in return have a higher impact on the environment by needing a new product after a shorter amount of time.	
Key lessons learned	• The essential use concept can reduce the amount of requested and to be processed applications by excluding clearly non-critical and/or non-necessary uses or uses where alternatives are readily available.	

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	• Such Cases like this one can be taken as a starting point for the application of an essential use concept to further pressure for substitution in the remaining uses. • The essential use concept should bring concrete elements/definition which should be fulfilled for a use to be proven essential in the consideration of derogations/authorisations. This would increase the predictability and ease the administrative burden during the process as currently no such elements are defined. • The requests for exemption/the exemptions granted are currently getting more and more specific, which on one hand leads to production as a whole potentially becoming unattractive due to fragmentation; on the other hand it also highlights cases which cannot be substituted. • The separation of use and associated product is often difficult for the assessment of necessity/criticality , especially in the medical sector. For example, DEHP most often fulfils the role of plasticiser, which in many cases would be labelled as non-essential however its use in certain medical equipment is necessary for such equipment to reach the required functionality. Hence, it can be expected that the use of well-defined elements for the horizontal guidance for the essential use concept (see Section 3 of Part B) will enable a clear understanding of what will be considered 'necessary or 'critical in this context.
References	COCIR, (2018). Exemption Request Form – DEHP in ion selective electrodes for point of care analysis of ionic substances in human body fluids. COCIR, (2019). Exemption Request Form – DEHP in plastic components in MRI detector coils. Oeko-Institut e.V. (2012). Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU, Available at: https://environment.ec.europa.eu/system/files/2021-01/Guidance_Document.pdf Oeko-Institut e.V., (2020). Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for bis-(ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care analysis of ionic substances in human body fluids; and request for a new exemption for DEHP in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils (Pack 17) – Final Report. PubChem, (2022), Bis(2-ethylhexyl) phthalate, Bis(2-ethylhexyl) phthalate | C24H38O4 - PubChem (nih.gov).

6. Trichloroethylene under EU Taxonomy legislation

Case study name	**Trichloroethylene under EU Taxonomy legislation**
Introduction	This case study considers how the essential use concept could be applied under a specific relevant aspect of the Taxonomy Regulation[48]. The case study looks at how the essential use concept might impact the process of assessing whether an economic activity / investment qualifies as environmentally sustainable (specifically with reference to the use of hazardous chemicals)compared to the situation in the absence of such a concept. This is looked at in relation to uses of a specific chemical substance, trichloroethylene, which has been subject REACH authorisation.
Research questions for case study	**Overall objective** – To assess how the essential use concept would have been used in this situation, and to investigate how it could have impacted this case, specifically concerning the definition and interpretation of specific provisions under the Taxonomy legislation, e.g. improved the effectiveness and efficiency of the process, the level of protection for health/environment, legal certainty, predictability, incentives to substitution, etc. The main objective of this task is to help elaborate the horizontal concept in Task 3. In this particular case, not all of these aspects can be directly compared (see below). It is noted that this case study relates to specific aspects of the Taxonomy legislation and consideration of essential use. The Taxonomy legislation is a relatively 'new' piece of legislation where there are yet to be 'decisions' made regarding manufacture/use/placing on the market of chemicals substances. Therefore, it is not possible for this case study to take a 'comparative' view of the 'current' situation and a scenario where the essential use concept is used. The focus here is on how the implementation of the horizonal essential use criteria could impact the overall effectiveness and efficiency of the regulation of 'the most harmful chemicals' under this legislation. In this case, this is not strictly related to the 'regulation' of chemicals, but rather the definition and interpretation of environmental criteria under the Taxonomy legislation to assess the sustainability of economic activities. Main high-level questions: ● How could the main elements of the essential use concept (necessity/criticality/lack of alternatives) have been assessed in this specific case to inform a decision?

[48] Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088.

Case study name	**Trichloroethylene under EU Taxonomy legislation**	
	• What are the key practical challenges in applying the essential use concept to this particular case? • What would be the impacts if the essential use concept were applied in this case – health/environment, economic, societal? • What key lessons can we draw from this case for implementing the essential use concept?	
Information sources and line of evidence	**Literature review**	The publicly available sources reviewed in the development of this case study include: • Legislative text relating to the Taxonomy Regulation and related Delegated Regulations. • ECHA web pages and published documentation relating to the Authorisations granted for trichloroethylene under REACH. • Further published reports (e.g. by ECHA) and journal articles relating to trichloroethylene. Full details of references used throughout the case study are provided in the reference list below.
	Consultation	• Discussion with key Commission staff
	Other Sources	N/A
Background context	**Legislation**	Regulation (EU) 2020/852[49] (The Taxonomy Regulation) on the establishment of a framework to facilitate sustainable investment, and relevant delegated regulations[50]. This case study specifically relates to Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021 supplementing Regulation (EU) 2020/852 (The EU

[49] Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088.
[50] European Commission. EU taxonomy for sustainable activities. Retrieved 2022-11-24 at: https://ec.europa.eu/info/business-economy-euro/banking-and-finance/sustainable-finance/eu-taxonomy-sustainable-activities_en.

Case study name	Trichloroethylene under EU Taxonomy legislation	
		Taxonomy Climate Delegated Act)[51]. Further specific detail regarding the specific situation regarding TCE under the Taxonomy Regulation is provided below.
	Chemical Substance	Trichloroethylene (TCE) (EC No 201-167-4; CAS No 79-01-6) As discussed in ECHA (2022), TCE was added to the list of substances included in Annex XIV of REACH ("Authorisation List") on the basis of carcinogenic properties (Article 57a) in April 2013[52]. Unless an authorisation application was submitted, companies therefore had to cease their use of TCE by the sunset date of 21 April 2016.
	On use/function	TCE is most notably used as a solvent for cleaning and degreasing metal parts. Other key uses have included use as an anaesthetic, a heat-transfer medium, an extraction agent for fats and oils, as an intermediate in producing chlorofluorocarbons and other chemicals, and as an ingredient in many products for industrial and consumer use (e.g. adhesives, paint removers, typewriter correction fluids, and spot removers) . As of January 2022, authorisations for 18 uses of TCE had been granted by the European Commission to 11 companies, 15 of which were still valid to date.[53] It is noted that the authorisations predominantly cover the use of TCE as solvent across a wide number of different process and applications (e.g. extraction, cleaning)[54]

[51] Commission Delegated Regulation (EU) 2021/2139 of 4 June 2021 supplementing Regulation (EU) 2020/852 of the European Parliament and of the Council by establishing the technical screening criteria for determining the conditions under which an economic activity qualifies as contributing substantially to climate change mitigation or climate change adaptation and for determining whether that economic activity causes no significant harm to any of the other environmental objectives.
[52] Commission Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
[53] March 2022.
[54] Authorised uses include: Use in industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist ; Industrial use as process chemical (enclosed systems) in Alcantara Material production ; Use in packaging; Use in formulation; Use as extraction solvent for bitumen in asphalt analysis; Solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers; Solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries; Use in vulcanising and bonding agents for endless connections and repair of chloroprene rubber coated conveyor belts in underground hard coal mining; Solvent for the purification of caprolactam from caprolactam oil.

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	On the current situation	Regulation (EU) 2020/852 (The Taxonomy Regulation) establishes the general framework for determining whether an economic activity qualifies as environmentally sustainable for the purposes of establishing the degree to which an investment is environmentally sustainable. Under this, the Commission has established a list of environmentally sustainable activities by defining technical screening criteria for each environmental objective through delegated acts. Appendix C[55] to Commission Delegated Regulation (EU) 2021/2139 specifies a generic criteria for do no significant harm (DNSH) to pollution prevention and control regarding use and presence of chemicals. The DNSH criteria ensures that substances that meet the criteria for substances of very high concern (SVHC) are not manufactured, placed on the market or used, except where their use has been proven to be "essential for the society". As TCE is listed as a SVHC under REACH, it would therefore not fulfil the criteria for DNSH unless demonstrated to have uses that are 'essential for the society'. This case study will therefore consider if/how the implementation of the 'horizonal' essential use concept would impact the overall effectiveness and efficiency of decision making in the context of the Taxonomy Regulation, using the case of TCE as an example.
Application of Essential Use Concept Criteria	**Feasibility**	In terms of general scope, there are two key points of consideration for application of the 'essential use concept' in the context of the Taxonomy Regulation: **1) On the 'classification' of chemical substances covered.** The Appendix C criteria under the Taxonomy Regulation applies to substances meeting the criteria for SVHCs (as defined under Article 57), while the essential use concept is expected to be applied to 'the most harmful substances'. In practice, it is expected that substances meeting the criteria for SVHCs under REACH will be considered to meet the description of 'the most harmful substances', so the two definitions should in theory align. There should not be any risk of non-alignment between the two if the essential use concept was applied under Taxonomy Regulation.

[55] Generic criteria for DNSH to pollution prevention and control regarding use and presence of chemicals

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	2) On the definition and criteria of 'essential' use It is noted that the terminology is not consistent between the DNSH criteria under Appendix C and the essential use concept. The essential use concept defines the criteria for a use to be deemed 'essential'. i.e. demonstrating the use is 'necessary for health or safety and/or is critical for the functioning of society AND there are no alternatives that are acceptable from the standpoint of environment and health . This in practice can define how to interpret the term 'use essential to the society' in Appendix C. If the essential use concept were not applied horizontally, e.g. only in REACH and not in other legislation, because the description used in the Taxonomy regulation refers only to the broader term 'essential to the society', this could potentially risk of poor alignment, if for example, a different criteria were to be used under the DNSH criteria in Appendix C. The application of the essential use concept could therefore make the process less burdensome and more predictable for industry, particularly when this is a 'self-regulated' process (see below). In practice, it is envisioned that the concept would be used 'horizontally' and the same criteria used, as developed for REACH. If applied this way, it could be viewed as a more efficient system.
Challenges	It is noted that, the process for demonstrating compliance with the DNSH criteria under the Taxonomy Regulation is a 'self-regulated' process for industry to follow. A key to successful implementation (as well as enforcement/monitoring) will therefore be provision of clear horizontal and legislation-specific guidance to industry to fully understand the process and the requirements for demonstrating what is 'essential for the society' in this context. Clearly development of clear criteria and guidance for the horizontal essential use concept, and possibly also a more legislation-specific guidance document under REACH, that to a large extent would be applicable here, would make this more efficient and effective (see below). In the absence of the horizontal essential use concept here, there would be a need to develop a completely separate guidance and potentially with a different interpretation of what 'a use essential for the society' means and how this is to be interpreted and applied within DNSH criteria. This runs the risk of a) leading to decisions on what is 'essential' that are inconsistent between different regulatory regimes; b) leading to greater burden on the Commission and relevant authorities to develop additional guidance, and industry to develop the required data or

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information (see below); c) more uncertainty and confusion for different actors in terms of what constitutes ‘an essential use’.

In terms of applying the essential use criteria, i.e. i) demonstrating necessity for health/safety or criticality for the functioning of society, and ii) assessment of alternatives, the case of TCE demonstrates the complexity of making this assessment. It was noted above that there have been a number of different authorised uses for TCE under REACH. These authorisations have been approved on the basis of the socio-economic benefits outweighing the risk to human health. Obviously under the essential use concept, it is expected that considerations for what uses are considered to comply with the DNSH criteria for taxonomy purposes would be based on consideration of ‘essential use’, including:

Necessity for health/safety or criticality for the functioning of society

It is expected that the applications of TCE most relevant in the taxonomy context would be related to industrial uses. Examples of industrial uses can be found in REACH authorisations:

- Use in Industrial Parts Cleaning by Vapour Degreasing
- Use as Extraction Solvent for Bitumen in Asphalt Analysis

It is unclear if these specific uses could be considered ‘essential’. To meet the criteria, for example, it would need be demonstrated that the use of TCE was required to fulfil the necessary function in these uses to deliver a practical application which is ‘necessary for health/safety’ or ‘critical for the function of society’ (for example, in these cases, this could include the cleaning of parts or conducting analysis to a level of performance that is required meet a specific safety or performance standards).

As detailed in Section 3 of Part Bi in this report, it is envisaged the essential use criteria will be accompanied by clear horizontal guidance, detailing the elements to define what is ‘necessary’ and ‘critical’.

lack of available alternatives Demonstrating the lack of alternatives is a key component of essential use criteria and it is expected this will also apply when considering ‘essential to the society’ under the Appendix C criteria.

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		For most 'industrial' uses of TCE, the assessment of alternatives (e.g., availability, technical and economic feasibility) would be based on the 'use' e.g., as a solvent, including the consideration of products into which TCE is incorporated. ECHA (2022) observed that in some cases, safer alternatives to TCE have been introduced while, for example, switching to other highly hazardous degreasers – such as perchloroethylene – may have introduced other risks to human health and the environment and hence, lead to a regrettable substitution. Replacement of TCE by perchloroethylene would therefore under the essential use concept not be acceptable from the point of environment and health, equally as it had not been considered a suitable alternative under REACH. What is clear from this example of TCE, is that the consideration of what is 'essential' or not is not always evident and would in many cases require careful assessment. It is logical to consider that industry would welcome clear, consistent criteria to understand and navigate this also in the taxonomy context. While it is not envisaged that decisions regarding derogations made under REACH or other legislation, on the basis of essential use concept would automatically be applied under Taxonomy legislation (i.e. to demonstrated compliance with Appendix C criteria), it might be beneficial to apply a 'horizontal essential use concept across different pieces of legislation.
Potential impact of the ESU in this case	**Administrative burden**	As discussed above, the criteria for demonstrating and assessing essential use applied horizontally in different pieces of legislation can also be used to interpret the DNSH criteria in taxonomy (Appendix C) which is key in this respect. Well defined horizontal guidance would potentially present relatively low administrative burden (to the Commission, authorities, auditors and industry). The more diverged the system under Appendix C is from the horizontal essential use concept, the more potential burden there could be in relation to the taxonomy implementation. It is expected there would a need to have an adequate 'audit' capacity to make judgements on cases of perceived 'essential' uses. This would in theory require relevant qualification/experience/accreditation. It is not clear who would be responsible for this, or how these assessments/decisions under taxonomy could best be aligned with the application of the essential use concept under other legislation (e.g. REACH). It should be noted, this alignment would be required regardless of the application of the essential use concept so does not represent a significant difference between the two situations.

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	Timing of procedure	It is noted that the Taxonomy Regulation is a relatively 'new legislation', so it is not strictly possible to compare with the 'existing' procedure. As discussed above – a well aligned process between the essential use concept, as might be applied under REACH (under revision), and under the Taxonomy Regulation could result in a quicker overall process for assessing cases of 'essential' use. In the absence of the horizontal essential use criteria (and corresponding guidance), companies self-regulating the DNSH criteria under Appendix C may not be aware how and what basis to make this assessment, so would potentially require additional support or consultation with the Commission or authorities to navigate the process.
	Simplification of the regulatory procedures	It is noted that there may be a need to revise/clarify the current legal text of the Taxonomy Regulation and Delegated Regulation, for example to clarify the link to or include the criteria and definition of 'essential for the society' from the horizontal essential use concept. It is noted that Art. 19 (EU) 2020/852 specifies that Commission shall review the technical screening criteria for those activities at least every three years, hence this offers the potential to make necessary changes/clarifications in the criteria within the existing legal provision of the Regulation, so no significant additional burden would be required. The horizontal essential use criteria, would make the implementation of the criteria for do no significant harm (DNSH) under the Taxonomy Regulation clearer to industry. It is emphasised that there would be a need to make the guidance as clear as possible. Diverging from this would potentially add unnecessary complexity. Looking at the process from the other way, one aspect to note is the potential information about alternatives to 'the most harmful substances' that could be generated under the Taxonomy Regulation. It could be expected that, when the full pollution prevention criteria (currently in development) are finalised, this could lead to companies providing valuable information for potential substitutes to harmful chemicals. This could then feed into the assessments of essential use performed under other regulatory regimes and aid the horizontal application of the concept.
	Predictability	As discussed above, a well-aligned system would be seen as more predictable and lead to more uniform process. Any divergence could mean less predictability and higher uncertainty in terms of how essential use is defined and assessed.
	SMEs	As SMEs would be expected to have more limited financial and labour resources available to devote to regulatory compliance, it would be logical to expect they would benefit more from a well-aligned horizontal system and could be disproportionally impacted by divergence or inconsistency between different pieces of legislation.

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	Sector-specific	Some sectors may be more impacted than others. The specific examples for the uses of TCE where this may be considered 'essential for the society' are expected to be relevant to industrial sectors, however it is noted the taxonomy provisions would not only be limited to industrial uses.
	Geographic	N/A – expected to be applied at Union-level
Existing gaps in knowledge	• Noted this is a relatively 'new' piece of legislation, so some uncertainty remains and no information has been obtained from 'existing' cases. • The 'pollution prevention' criteria under the Taxonomy Regulation is currently being developed.	
Key lessons learned	• Implementing the essential use concept to interpret the DNSH criteria under the taxonomy regulations offers key advantages in terms of the overall effectiveness and efficiency of the regulation of harmful chemicals. • Diverging systems for assessing 'essential use' between the two regimes could potentially result in more administrative burden, more uncertainty and weaker restriction of chemicals. • The TCE example demonstrates that the determination of 'essential' uses, both in terms of 'necessity/criticality' and lack of alternatives could be relatively complex. While for some cases that are more 'clear cut' a relatively easy assessment could be made on the issue of essential use, it is unlikely the uses of TCE would fall into this category. Hence having a well-aligned 'horizontal' system would be beneficial in this case. • The information on potential alternatives derived from the Taxonomy Regulation could be feed into the assessments under other regulations, hence improving the overall coherence across the concept.	
References	ECHA (2022) Impacts of REACH authorisation of trichloroethylene (TCE): State of play in January 2022. Available at: https://echa.europa.eu/documents/10162/17228/report_tce_authorisation_en.pdf/b5a4ba04-6f04-dcc5-f5b2-c1bb880d4152?t=1648189225768.	

7. Anticoagulant rodenticides under the Biocidal Products Regulation (BPR)

Case study name	**Anticoagulant rodenticides under the Biocidal Products Regulation (BPR)**	
Introduction	This case study focusses on the derogations approved under the BPR for a number of specific anticoagulant rodenticides. As the present project to support the development of the essential use project does not include the BPR under the scope of legislation covered, this case study looks to draw out key lessons learnt in the consideration of 'essential' uses in the assessment of potential derogations for the most harmful substances.	
Research questions for case study	It should be noted that this case study takes a different approach compared with the other case studies presented in this section. Where other case studies in this section have looked hypothetically how the application of the essential use concept could have impacted existing cases, this case demonstrates an example of where a derogation from a restriction/prohibition of a chemical has been approved on the basis of demonstrating 'essential use' (as defined under the BPR). Therefore, the focus here has been to draw out any key 'lessons' to be learned from this example, for how the essential use concept can be effectively defined and implemented in wider chemicals regulation. Main high-level questions: ● How were the main elements of the essential use concept (necessity/criticality/lack of alternatives) assessed in this specific case to inform the decision? ● What were the key practical challenges in applying the essential use concept to this particular case? ● What key lessons can we learn from this case for implementing the essential use concept?	
Information sources and line of evidence	**Literature review**	Key publicly available documents reviewed: ● The ECHA (2017) Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on Questions regarding the comparative assessment of anticoagulant rodenticides, ECHA/BPC/145/2017 ▸ Key legislative text related to this case – including European Commission (2017) Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of

Case study name	Anticoagulant rodenticides under the Biocidal Products Regulation (BPR)	
		[brodifacoum/bromadiolone/chlorophacinone/coumatetralyl/difenacoum/difethialone/flocoumafen/warfarin] as an active substance for use in biocidal products of product-type 14. • ECHA BPC Opinion documents[56]. • Commission Assessment Reports on applicable anticoagulant rodenticides[57].
	Consultation	• Discussions were held during initial targeted interviews with the departments and desk officers of the Commission responsible for this legislation.
	Other Sources	N/A
Background context	**Legislation**	This case study concerns Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (the Biocidal Products Regulation). Under the BPR, biocidal products are regulated at two levels: i) through the approval of active substances used in biocidal products, and ii) through the authorisation of biocidal products themselves. The approval of active substances must occur prior to the authorisation of biocidal products containing these active substances. An evaluating Member State competent authority must initially assess the active substances before forwarding the results of their evaluation to ECHA's Biocidal Products Committee. The opinion generated by ECHA's Biocidal Products Committee is used by the European Commission in their decision on approval.

[56] European Chemicals Agency, ECHA. Biocidal Products Committee opinions on active substance approval. Retrieved 2022-11-24 at: https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval?p_p_id=viewsubstances_WAR_echarevsubstanceportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&_viewsubstances_WAR_echarevsubstanceportlet_orderByCol=staticField_-104&_viewsubstances_WAR_echarevsubstanceportlet_orderByType=asc&_viewsubstances_WAR_echarevsubstanceportlet_resetCur=false&_viewsubstances_WAR_echarevsubstanceportlet_delta=200.

[57] European Chemicals Agency, ECHA. Information on biocides. Retrieved 2022-11-24 at: https://echa.europa.eu/information-on-chemicals/biocidal-active-substances/-/disas/factsheet/18/PT14.

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	On substance (and its alternatives)	Anticoagulant rodenticides – specifically those that have been approved within the BPR following their derogation from Article 5(1) under Article 5(2), including: brodifacoum[58], bromadiolone[59], chlorophacinone[60], coumatetralyl[61], difenacoum[62], difethialone[63], flocoumafen[64] and warfarin[65]. The alternative authorised biocidal products with the same uses as the anticoagulant rodenticides include alpha chloralose, aluminium phosphide releasing phosphine, hydrogen cyanide, carbon dioxide, and powdered corn cob. Non-chemical alternatives to the current uses of anticoagulant rodenticides (and indeed biocidal products in general) include electrical rodent traps, glue board, mechanical traps and shooting. Preventative measures include habitat modification, rodent-proofing and ultra-sound (ECHA, 2017).
	On use/function	Anticoagulant rodenticides are commonly used as baits for the control of rat and mouse populations. They are used by different categories of user including the general public, professionals and trained professionals[66]. Specified uses referred to in Article 23(3)(a) of Regulation (EU) No 528/2012 are to treat *Mus musculus* (house mice), *Rattus norvegicus* (brown rat), and *Rattus rattus* (black or roof rat) populations. The fields of use include indoors, outdoors and in sewers[67].
	On the current situation	The CLP classification for the above-mentioned anticoagulant rodenticides identifies these substances as either reproductive toxins category 1A or 1B. As they therefore fulfil the 'exclusion criteria', they would ordinarily not be approved under the BPR in accordance with Article 5(1). Article 5(2) provides a derogation to allow the approval of active substances if they meet at least one of the following conditions:

[58] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of brodifacoum as an active substance for use in biocidal products of product-type 14.
[59] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of bromadiolone as an active substance for use in biocidal products of product-type 14.
[60] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of chlorophacinone as an active substance for use in biocidal products of product-type 14.
[61] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of coumatetralyl as an active substance for use in biocidal products of product-type 14.
[62] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of difenacoum as an active substance for use in biocidal products of product-type 14.
[63] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of difethialone as an active substance for use in biocidal products of product-type 14.
[64] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of flocoumafen as an active substance for use in biocidal products of product-type 14.
[65] Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of warfarin as an active substance for use in biocidal products of product-type 14.
[66] Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.
[67] Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

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a) *The risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst-case conditions of use, is negligible;*

b) *It is shown that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment;* or

c) *Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.*

The anticoagulant rodenticides were determined to meet criteria b) and c) (see Implementing Acts detailed above), so the active substances were approved, with the substances listed as 'candidates for substitution',
With respect to the Union authorisation process for the biocidal products, Article 23(3) of the BPR states that: a biocidal product containing an active substance that is a candidate for substitution must be restricted or prohibited if a comparative assessment demonstrates that both of the following criteria are met:

a) *for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages.*

b) *the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism*.

The 60th meeting of representatives of Member States Competent Authorities for the implementation of the BPR led to a series of questions that were submitted by Member State competent authorities to the Commission. These questions were to be addressed at Union level and were on the topic of the comparative assessment to be carried out at the renewal of approvals for anticoagulant rodenticides. As there was large number of these products (>3000) undergoing renewal, the comparative assessment of the group as a whole was referred to the Commission.

As shown in the assessment report(s), the use of these anticoagulant rodenticide-based biocidal products has been approved on the basis of the evaluation as product-type 14 (Rodenticides), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of the BPR concerning the placing of biocidal products on the market, with a view to the possible inclusion of this substance into Annex I or IA to the Directive. This is on condition of applying several additional risk management measures (see below).

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Application of Essential Use Concept Criteria

Feasibility

Demonstrating necessity for health or safety / criticality for functioning of society

As discussed in earlier sections, it is clear the criteria used to assess the justification for derogations for the anticoagulant rodenticides under the BPR here is broadly very similar to, and aligns with the criteria set out for the essential use concept – see comparison table below:

Biocidal Products Regulation	Essential use Concept
Essential to prevent or control a serious danger to human health, animal health or the environment. OR c) Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.	Necessary for health/safety OR Critical for the functioning of society
AND If another authorised biocidal product or a non-chemical control or prevention method [DOES NOT] already exist which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages.	No acceptable alternatives from the standpoint of environment and health.

In practice, a key difference is that the first part of the assessment under the BPR (necessity/criticality) is on the basis of the active substance, while the second part (assessment of alternatives) is carried out on the basis of biocidal products.

It is noted that, from the assessment report, the justification of Article 5(2) compliance for the anticoagulant rodenticides is due to the 'purpose of the protection of public health', specifically:

- Prevention of transmission of disease;
- Prevention of the contamination of food and feeding stuffs;
- Protection of buildings and structures including pipes, cables and overall integrity as well as prevention of structural damage and social abhorrence; and
- Protection of livestock, wild and domestic

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The assessment reports also list specific locations of use, e.g. 'In and around buildings, sewers, open areas, waste dump (landfill), agricultural control of rodents indoors (i.e. in grain silos, warehouses), in and around farms.

This case clearly provides some specific examples of what has shown to be relevant in terms of being "necessary for health or safety" when assessing derogations for the most harmful substances.
In terms of the assessment of alternatives, a comparative assessment is carried out based on the evaluation of alternatives for the uses that have been specified in an application for product authorisation or renewal, The comparison assessment covers the following aspects:

- Is the chemical diversity of the active substances in authorised rodenticides in the EU adequate to minimise the occurrence of resistance in the target harmful organisms?
- For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?
- Are these alternatives sufficiently effective?
- Do these alternatives present no other significant economic or practical disadvantages?
- Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?

From these assessments, it was stated that: "Other, more humane control methods are available: alternative active substances or biocidal products as well as non-chemical alternatives. However, as there are concerns whether these alternatives are sufficiently effective or do present other practical or economical disadvantages, anticoagulant rodenticides containing biocidal products should be accepted".

Therefore, the approval of derogations for the anticoagulant rodenticides has been made, partly on the basis of the absence of sufficiently 'effective' alternatives. The approval reports also include the provision that "a more detailed risk benefit analysis should be made as part of the comparative assessment when more information is available on alternative substances".

Lack of available alternatives:

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It is noted that in November 2022, ECHA's Biocidal Products Committee (BPC) adopted its opinion on the comparative assessment for the second renewal of all anticoagulant rodenticides in the EU[68]. In summary

Non-chemical alternatives:

- Mechanical traps used by the general public and (trained) professionals to control house mice indoors are considered effective.
- Use of these traps in this setting does not present significant practical and economical disadvantages and will result in a significantly lower risk for human and animal health and for the environment compared to anticoagulant rodenticides.
- It was recommended to obtain more information to confirm the conclusion, as the available test did not consider different infestation situations (for example types of building, types of traps and levels of infestation).
- The BPC could not conclude on whether mechanical traps are effective for permanent baiting.

Chemical alternatives:

- Cholecalciferol and alphachloralose were considered suitable for controlling house mice and for permanent baiting indoors when done by professional users.
- The BPC could not conclude that cholecalciferol and alphachloralose have a significantly better hazard profile for human health, animal health and the environment compared to the anticoagulant rodenticides.
- Carbon dioxide was considered suitable for mice control by trained professionals for permanent baiting indoors. It has a significantly lower overall hazard profile and risk compared to anticoagulant rodenticides.

As part of the decision, It was noted that, *"for the use and effectiveness of rodent traps for indoor control of mice, we had one test available. This test was carried out according to existing EU guidance. The committee discussed if one*

[68] ECHA (2022), Rodent traps can be effective at controlling house mice infestations, ECHA/NR/22/19, Accessed 06/12/2022 from: https://echa.europa.eu/-/rodent-traps-can-be-effective-at-controlling-house-mice-infestations?utm_source=echa-weekly&utm_medium=email&utm_campaign=weekly&utm_content=20221130&_cldee=AO7GECVm7P9rsn3FYMmSEICxZksq9xshb3m3k54XHS2bC4FVQUihmmz_9idBvTUb&recipientid=contact-0ba80362cc5ce81180fe005056952b31-cbb07711102a4d15b29422221421f36e&esid=270d54f9-a670-ed11-8143-005056b9310e

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		test is sufficient, but as it proved that the trap used was effective, we concluded that rodent traps are suitable alternatives."
	Challenges	While the discussion above shows how the consideration of 'essential' use aligns very strongly between the two systems, there are a number of aspects that would make the application of 'essential use' as set out in the BPR for purposes of the horizontal 'essential use concept' more challenging: • As mentioned above, the BRP regulatory process is quite different compared to REACH and other chemicals legislation – e.g. the separate approvals/authorisations for active substances and biocidal products; different assessment process (e.g. assessment made by Member State Authority with further input from Biocidal Products Committee of ECHA). Therefore, it is not clear how this existing system for providing derogations under the BPR would directly translate to other regulatory regimes. • While the derogations for these substances have been approved, the assessment reports note that there remain 'unacceptable risk for secondary poisoning of the non-target vertebrates and risk for secondary exposure of humans'. Therefore, the approvals were contingent on a number of additional risk management measures that must be applied when using these products (e.g. maximum nominal concentration; use of an aversive agent or dye; minimised exposure of humans, non-target animals and the environment e.g. restriction to professional use; specific instructions for use, use of PPE etc). • As discussed above, in establishing the effectiveness of alternatives to the anticoagulant rodenticides there were some challenges due to the lack of available data. For example, there was a lack of data to allow ECHA to determine how the size of an infestation affects the efficacy of each non-chemical method of control. For several of the non-chemical alternatives there was a lack of information from literature and public consultations. There was also a lack of information available on the efficacy of electrical rodent traps and so it had to be considered insufficiently effective at providing a similar level of protection and control as anticoagulant rodenticides. There were also limited scientific references for the efficacy of glue boards as well as how humane this technology is. A similar lack of scientific data for mechanical traps was present (ECHA, 2017).
Potential impact of the ESU in this case	**Administrative burden**	Under the BPR, an assessment is required for each active substance on a substance-by substance basis, with the burden of proof on the industry applicant, as is envisioned for the application of the essential use concept. In the case of the assessment of criticality/necessity, this involves provision of (and assessment of) data to justify a derogation on a broadly similar criteria as set out for the essential use concept (see above) i.e. around the need to maintain public health. In the case of the assessment of alternatives, there are more specific requirements and

Case study name	Anticoagulant rodenticides under the Biocidal Products Regulation (BPR)	
		provisions for the comparative assessment under the BPR (e.g. economic and practical disadvantages), which are not explicit in essential use concept as set out in the CSS. It is noted that some aspects of how the process under the BPR is carried out helps to reduce the administrative burden: ● It is noted that some of the data provided by the applicant in step 1 of the process (demonstrating the essential use of the active substance) can then also be used step 2 (comparative assessment of alternatives), thus alleviating the need to 'duplicate' data inputs for applicants. ● As several anticoagulants have been assessed at the same time, being quite similar regarding the hazardous properties and associated risks, some parts of the assessment were able to be conducted in parallel, reducing the overall time and burden taken. For example, the Commission initiated work on possible risk mitigation measures for all anticoagulant rodenticides simultaneously. This latter point is an example of where aspects of the assessment of essential use could be grouped for multiple similar substances. Even though an individual assessment is required for each substance (as is envisaged for the essential use concept), where the properties/functions of multiple substances are similar, this approach could be beneficial and make the process more efficient.
	Timing of procedure	While the process of applying for the derogation can take a long time, it is also seen as important to be thorough in terms of not allowing 'easier' derogations which could undermine the aim of the legislation. To ensure acceptable timeliness of the procedure, some (not all) of the steps involved in the assessment and decision-making are subject to time limits. For example, ECHA opinions are required within 9 months, but no limit is placed on the Commission to provide the final decision.
	Simplification of the regulatory procedures	It has been highlighted by DG SANTE that the onus of demonstrating essential use (in this case of the anticoagulant rodenticides) is placed on the applicant which improves the efficiency of the regulatory process. It was highlighted that this process produces an economic incentive for proving that a substance meets the criteria for essential use and that it also simplifies the process of applying the essential use concept. The responsible directorate (DG SANTE) indicated that whether the essential use concept, or components thereof, simplify and/or speed up decision making depends on several factors. For example, the Commission would not want to make it easier to gain derogations and by its nature, the process of collating data for assessing derogations is a time-intensive process. It was indicated that the burden of proof should be on the applicant, as is the case under Article 5 of the BPR. Furthermore, it was noted that no two cases in which the essential use concept could be applied are the same. For example, the situation would be very different between biocidal products being used in

Case study name	Anticoagulant rodenticides under the Biocidal Products Regulation (BPR)	
		public hygiene compared to products used in infrastructure. It was noted that the depth of assessment regarding essential use is a fine balance between the depth of the assessment and the risk of increasing administrative burden. Finally, it was highlighted that essential use may be very different for different uses (for different reasons). These considerations are expected to similar, if not the same when applying the horizontal essential use concept. While in this case, there are aspects of the derogation process that have been made similar and more streamlined (as discussed above), in practice,
	Predictability	It is noted that within the BPR Article 5(2), there is no specific definition or guidance given on what constitutes either 'essential to prevent or control a serious danger to human health, animal health or the environment' or 'disproportionate negative impact on society'. It is noted that applicants can provide whatever evidence they determine demonstrates these aspects are met. In this sense, there could potentially be uncertainty for applicants. However, in this case this is not considered to have caused any problem or delay, and the justification for this component of the assessment was clear. In practice, the evidence to support the application for each of the anticoagulant rodenticides was broadly the same, indicting there was a common understanding of what aspects of the use of these substances were relevant in this case. To enable greater understanding and predictability relating to this particular case, the ECHA guidance 'Questions regarding the comparative assessment of anticoagulant rodenticides' was published prior to the renewal of the approval of these rodenticides as active substances under the BPR in 2017. This has enabled industry and users of anticoagulant rodenticides to transparently observe ECHA's opinion (and reasoning) on the essential use of anticoagulant rodenticides prior to any legislative changes. In general, it can be considered that a consistent assessment process has been applied across multiple similar substances. Input from the Commission has indicated this is generally a well-understood, transparent process that has been received well by industry (with no major dispute or appeals). For example, the process included public consultation (even though this was not required under the legislation). As discussed above, to enable a common understanding, and consistent application of appropriate risk management measures with the derogation, a document describing possible risk mitigation measures for all anticoagulant rodenticides has been developed - see European Commission (2014).
	SMEs	No specific mention of provisions in place to support SMEs has been made in this case, and no specific factors within this case that could make the process disproportionality costly or burdensome for SMEs have been raised.
	Sector-specific	Due to the generally poorer effectiveness of alternatives to the anticoagulant rodenticides, the derogation from Article 5(1) and subsequent approval of these active substances has benefitted several sectors. In particular, the

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		approval of the anticoagulant rodenticides following the application of the essential use concept has benefitted the food-handling sector (e.g. restaurants, supermarkets, food wholesales etc), accommodation (rental housing, hotels, hostels) and storage; these sectors are likely to have seen the biggest benefits. It is also likely that public sanitation departments would be impacted due to the use of the anticoagulant rodenticides in the sewer network (ECHA, 2017). A mixture of user categories have likely been impacted by the approval of the anticoagulant rodenticides via the application of the essential use concept. These categories are primarily the general public, professionals and trained professionals[69].
	Geographic	N/A – approval at Union level.
Existing gaps in knowledge	• It has been identified that there is a lack of available data on the effectiveness of alternatives to the anticoagulant rodenticides. This has been stated earlier as a challenge associated with the application of the essential use concept as it has made it harder to identify the availability of alternatives.	
Key lessons learned	• The process of considering derogations in this case broadly reflects the same considerations expected to be applied in the essential use concept, although some key differences are noted between the two processes. • This case has highlighted key examples of the criteria that can be applied to determine what is an 'essential' use of a substance in this context (e.g. prevention of transmission of disease; prevention of the contamination of food; protection of buildings and structures and prevention of structural damage; and protection of livestock). • In establishing the effectiveness of alternatives to the anticoagulant rodenticides there were some challenges due to the lack of available data. • The process for granting derogations under the BPR was (deliberately) relatively onerous because it may lead to continued use of and exposure to some of the most harmful chemicals. • Several aspects of the assessment have been carried out in such a way as to improve the efficiency and effectiveness of the process, including conducting some parts of the assessment in parallel, as the substances display similar hazards/properties/risks, leading to greater consistency between the decisions made, and the additional risk management measures applied.	

[69] European Chemicals Agency, ECHA (2017). Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on Questions regarding the comparative assessment of anticoagulant rodenticides. ECHA/BPC/145/2017. 2 March 2017.

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	• In general, this can be considered a 'success story' in terms of how derogations can be applied on the basis of 'essential use'.
References	ECHA (2017). Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on Questions regarding the comparative assessment of anticoagulant. European Commission (2014). 58th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products: Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2).

Appendix C
Stakeholder feedback on only applying the essential use concept for uses which are not 'safe'

This appendix is included to highlight the feedback from stakeholders on the scope of the essential use concept. Although not specifically explored in targeted surveys and questionnaires, many industry stakeholders have voiced their view on the potential consideration of 'safe use' in the context of the essential use concept, in particular, on whether the essential use concept should apply as the only ground to decide on derogations from restrictions and authorisations in which case non-essential uses should not be derogated/authorised, or whether the concept should only apply to uses which cannot be proved to be 'safe'.

The decision on whether 'safe' uses should be allowed in addition to essential uses is not considered under scope of defining the horizontal essential use concept or setting the policy options for implementation. Rather, it is being considered separately by the Commission who is assessing the grounds for exclusions from restrictions under individual pieces of chemicals legislation. In the revision of REACH, the Commission is assessing and considering as an option that in certain exceptional cases, the derogations from restrictions might also be envisaged on the basis of minimal exposure throughout the life cycle.[213]

Given that this decision is beyond the scope of this project, the information presented in this appendix does not include recommendations, but summarises the evidence related to the 'safe use' argument received under the consultation of this project, in order to help the Commission in their broader consideration of whether exclusions/derogations from restrictions could also be envisaged on the basis of minimal exposure.

The most common suggestion to refine the scope of the concept was to not focus on all uses of the most harmful chemicals (as stated in the CSS), but instead, limit the application to only uses which cannot be demonstrated to be 'safe', based on the opinion of some industry representatives that for some uses of the most harmful chemicals, risk management measures can be sufficient to avoid risks to human health and the environment, and therefore, there is no need to ban these uses as they do not pose a threat to the objectives of the CSS, i.e., some stakeholders view that certain uses of the most harmful chemicals do not negatively impact both humans and the environment over their lifecycle, so their restriction would have no effect on the goal to protect humans and the environment.

Arguments from industry that the most harmful chemicals should not be banned by default are not only relevant in the context of the essential use concept, but in relation to the overall extension of GRA as proposed in the CSS. Stakeholders suggest that both essential use and safe use are applied to justify derogations from bans. As such, the safe use concept is beyond the scope of this project and is being further explored separately by the Commission and other contactors. Under this project, safe use considerations have been discussed in order to reflect the large number of comments from stakeholders in all consultation activities.

Importantly, there is a wide divide between stakeholders on this matter. While we have not quantitatively examined this divide, a review of the position papers received by the project team

[213] European Commission (2022). CA/45/2022 45th Meeting of Competent Authorities for REACH and CLP (CARACAL). 28th June 2022.

revealed a high degree of support for the 'safe use concept' from most industry representatives, but strong resistance from some NGOs and competent authorities from one Member State who argue that use of one of the most harmful chemicals can never be safe (e.g. due to environmental and consumer exposure which may occur due to emissions over the full chemical life cycle) and that current regulatory approaches which permit uses of chemicals for which risks are 'adequately controlled' (e.g. REACH Article 60(2)) are insufficiently protective. Notably, the number of NGOs and Member States commenting on 'safe use' was low, however, stakeholders were not specifically asked about this topic.

Arguments in favour of exemptions from restrictions of the most harmful chemicals for 'safe uses' suggested that this would make implementation of the essential use concept more defendable as bans of substances for which risks are low might result in unjustified and disproportionate impacts on industry. Industry representatives suggested that instead of generic bans for most harmful chemicals with exemptions for essential uses, most harmful chemicals should only be banned when safe use cannot be demonstrated, i.e., bans for non-essential uses would be a last resort risk management option after all other options to demonstrate acceptable risk have failed.

It should also be noted that no (proposed) definition of 'safe use' was identified in the literature or consultation outputs.

The following use types were suggested for exclusion from the scope of the essential use concept:

- All professional and industrial uses
- Use as intermediates
- Low volume uses

Some stakeholders from industry suggested that all **professional and industrial uses** should be outside the scope of the essential use concept under the assumption that risks are sufficiently controlled in comparison to consumer uses. However, we note that this assumption may not hold true in many cases, as highlighted by the fitness check of the most relevant chemicals legislation (except REACH) (Commission staff working document SWD(2019)199[214]) which concludes that the lack of transition to less hazardous chemicals over the last decade may partly reflect the effectiveness of risk management measures in reducing exposures and risks, therefore reducing the incentive to substitute to less hazardous substances.[215] Furthermore, it was noted that where substitution is referenced in existing pieces of the EU chemicals legislation, it does not provide any qualitative or quantitative basis against which to assess the pace of substitution per se.

While there is evidence of reduced risks in occupational settings, there is still uncertainty regarding the self-assessments of safety done by manufacturers/downstream users etc., as these assessments are not systematically checked by public authorities. The fitness check states that there is insufficient information to conclude on the level of compliance (sufficiency of self-assessments of chemical safety in occupational settings).

Exemplary studies were identified in the scientific literature which raise concern regarding the safety of professional and industrial users. For example, Apatsidou et al. (2018) observed inadequate use of personal protective equipment and safety data sheets in a sample of professional users in Greece).[216] The 2018 REACH review as well as other academic studies further demonstrate issues with missing or incomplete information in safety data sheets (52% non-compliance for safety data sheets was reported by Member States), which limits the ability of

[214] European Commission, (2019). Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. COM(2019) 264 final. 25th June 2019.
[215] European Commission, (2019). Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. COM(2019) 264 final. 25th June 2019.
[216] Apatsidou et al. (2018). Safe use of chemicals by professional users and health care specialists. Available at: https://www.spandidos-publications.com/br/8/2/160.

professional users to identify and therefore implement appropriate risk management measures.[217] While the REACH review found that implementation of risk management measures has increased due to REACH, these mostly consisted of use of personal protective equipment and safety instructions; measures which are low in the hierarchy of measures under occupational safety and health legislation[218].

Furthermore, potential human and environmental exposure during the whole lifecycle of the chemical (beyond the workplace) should be considered. For example, exposure to the public/end-user and vulnerable groups for certain uses (in offices, schools, hospitals), and potential exposure to from the recycling of materials into new articles.

The majority of arguments for 'safe use' exemptions proposed that, rather than blanket exemptions, only those uses meeting certain conditions should be exempted. To further explore the argument, we examined the following use types for which a significant proportion of industry representatives have argued are 'safe uses':

Use of chemicals as **intermediates** in chemical processes (e.g. manufacturing) so that the chemical is entirely consumed and/or contained during the process, therefore there are no emissions of the substance, no waste containing the substance, and no trace of the substance is found in the final product. For example, of 508 PFAS substances with active registrations, 257 were for intermediate uses (e.g. production of surfactants).[219] Of the 20,600 completed REACH registrations, 6,000 are for intermediate use only.[220] REACH Regulation does not apply to non-isolated intermediates, while on-site isolated intermediates are exempted from REACH restriction and authorisation, and transported isolated intermediates are exempted from authorisation, therefore would not be under scope of the essential use concept under REACH. Some industry representatives suggested if chemicals are only used in very **low quantities / volumes**, the potential risks to human health and the environment may be presumed as very low because risks are dependent on the extent to which humans and the environment are exposed. Low volume uses under 10 tonnes per year make up 7,200 of the 20,608 completed REACH registrations at the time of writing, demonstrating that exclusion from the essential use concept would affect a significant proportion of REACH-registered substances.[221] It is not clear from the evidence pertained what tonnage value industry representatives think should be exempt (e.g. grams, kilograms or tonnes).

Although low volume uses may present relatively lower risks to humans and the environment, this is dependent on the substance and it should be further explored whether this means risks are negligible. For example, for substances classified as persistent, bioaccumulative and toxic (PBT) such as PFAS, even small volumes of emission to the environment can represent a risk through environmental persistence and potential for wide geographical spread, including locations far from the site of use (long range transport).

Research conducted by RPA (2017) estimated that current REACH exemptions relating to information requirements in registrations[222] for low tonnage substances incur costs to human health (through incidence of diseases, disorders and impacts) and the environment (through environmental pollution and impacts on ecological status).[223] Although not specific to essential use,

[217] DeMasi, A., Elston, H. and Langerman, N. (2022). Safety Data Sheets: Challenges for authors, expectations for end-users. *ACS Chemical Health & Safety*, 29(4) 369–377.
[218] European Commission, (2018). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the operation of REACH and review of certain elements. COM(2018) 116 final. 5th March 2020.
[219] European Chemicals Agency, ECHA, (2022). Annex XV Restriction Report.
[220] European Chemicals Agency, ECHA. REACH Registration Results. Retrieved 2022-11-22 at: https://www.echa.europa.eu/reach-registrations-since-2008
[221] European Chemicals Agency, ECHA. REACH Registration Results. Retrieved 2022-11-22 at: https://www.echa.europa.eu/reach-registrations-since-2008
[222] Toxicological and Ecotoxicological Information Requirements in Annex VII
[223] Risk and Policy Analysts, RPA (2017). Study to gather further information to be used in support of an Impact Assessment of potential options, in particular possible Amendments of REACH Annexes, to modify requirements for

the study notably concludes that human health and environmental benefits of addressing low tonnage substances are significantly larger than the costs. This would need to be further investigated not just for low tonnages under 10 tonnes per year, but for tonnages predicted from the uses argued to be 'safe', for example, the production volume for these substances may be a lot lower than 10 tonnes.

Low volume uses may also be problematic due to cumulative effects of chemicals. That is, impacts on humans and the environment from chemicals may occur due to repeated exposure to substances over time as well as mixture effects from co-exposure to multiple substances which can have additive effects. Moreover, a low volume use which is localised (not dispersive) may present local risks to humans (in particular manufacturers and downstream users) and/or the environment. The acceptability of risks from low volume uses should be further explored bearing this in mind, as well as the very long lifespan of some of the most harmful chemicals (e.g. those which are very persistent).

Overall, arguments against the safe use concept as a basis for exemptions from bans of the most harmful chemicals are based on stakeholder's concern (from some NGOs and Member State competent authorities from 8 Member States that:

- Safe use exemptions could undermine the essential use concept and hinder the CSS objectives, specifically, the objective to phase out **all non-essential** uses of the most harmful chemicals. That is, exempting safe uses could result in derogations from restriction and authorisations for uses of most harmful chemicals which are not necessary for health/safety, critical for the functioning of society, and/or which have available alternatives.
- It may not be possible to guarantee that use of one of the most harmful chemicals is safe, and beyond the use of the chemical, risks may occur during other stages of the chemical lifecycle (e.g. production and disposal). Stakeholders in the workshop noted that most harmful chemicals often cause problems during recycling, even if use is considered 'safe'. This is substantiated by evidence from the literature, e.g. recycling workers handling e-waste are exposed to higher levels of toxic metals (Julander et al., 2014)[224], accumulation of hazardous substances in secondary materials can negatively affect market value and downstream uses (Groh et al., 2019)[225]. Consumers and the environment may also be at risk of exposure through products made from recycled materials containing most harmful chemicals (e.g. carcinogenic polycyclic aromatic hydrocarbons in products made from recycled rubber[226]).
- One NGO noted in a position paper that 'safe use' considerations are reflective of historic approaches to chemical management which are theoretically appealing but practically not very successful due to uncertainties in risk assessments. A workshop participant from academia supported this view that current/ past approaches fail to ensure safety because of risk considerations. Examples of pesticides and PFAS were discussed to highlight that despite risk management measures, harmful chemicals continue to accumulate in the environment.

registration of low tonnage substances (1-10t/year) and the CSA/CSR Requirement for CMR substances in the framework of REACH.

[224] Julander, A., Lundgren, L., Skare, L., Grander, M., Palm, B., Vahter, M., Liden, C. (2014). Formal recycling of e-waste leads to increased exposure to toxic metals: An occupational exposure study from Sweden. Environment International, 73, 243–251.

[225] Groh, K.J. Backhaus, T., Carney-Almroth, B., Geueke, B., Inostroza., P.A., Lennquist, A., Leslie, H. A., Maffini, M., Slunge, D., Trasande, L., Warnhurst, A.M., Muncke, J. . (2019). Overview of known plastic packaging-associated chemicals and their hazards. *Science of The Total Environment*, 651, 3253–3268.

[226] Diekmann, A., Giese, U. and Schaumann, I. (2019). Polycyclic aromatic hydrocarbons in consumer goods made from recycled rubber material: A Review. *Chemosphere*, 220, 1163–1178.

- Safe use considerations may provide a loophole for industry to continue business as usual, implying that the essential use concept would not be effective in addressing the defined problem.

Fewer comments arguing against considering safe use alongside essential use (compared to those arguing for) were received, most likely because stakeholders were not asked to provide feedback on this topic and industry stakeholders provided it spontaneously. Therefore, the views do not demonstrate fair coverage of stakeholder opinions. A literature search identified a lack of evidence specifically on 'safe use'. The 2018 review of REACH found that most non-industry stakeholders defend and wish to strengthen GRA (indicating preference against safe use considerations). NGOs argued that the specific risk management approach shifts the burden of proof back to authorities and slows down the listing of SVHCs.[227]

One NGO further noted in a position paper that the only role for 'safe use' under the essential use concept should be as a required condition for essential uses, so that essential uses must minimise risk and ideally prove adequate across the life cycle (further explored under Part B of this report on criteria following the decision on essentiality).

[227] European Commission, (2018). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee. COM(2018) 116 final. 5.3.2018

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