ECONOMIC ANALYSIS OF THE IMPACTS OF THE CHEMICALS STRATEGY FOR SUSTAINABILITY

Summary Report

Report for: The European Chemicals Industry Council (Cefic)

Ref. ED14790

Ricardo Energy & Environment, Gemini Building, Fermi Avenue, Harwell, Oxfordshire, OX11 0QR, UK | +44(0)1235 75 3000 | ee.ricardo.com
Registered company no. 08229264 | VAT no. GB 212 8365 24

Customer:
European Chemicals Industry Council (Cefic aisbl)
EU Transparency Register n° 64879142323-90]

Customer reference:
ED14790

Views expressed in this report are not the official opinion or position of Cefic. The report is the outcome of Ricardo's assessment of the overall impact of the EU Commission's Chemicals Strategy for Sustainability (CSS) on the European chemical industry at EU27 level, based on public literature and data collected from companies producing or using chemical substances, in compliance with competition law. It is not a forecasting exercise, but an estimation of potential future impacts based on available data, a series of assumptions and uncertainties. It is aimed to inform the policy debate on the CSS.

While the report has been designed using the best knowledge currently available, it is to be relied upon at the user's own risk. No representations or warranties are made with regards to its accuracy or completeness, and no liability will be accepted by Ricardo nor Cefic for damages of any nature whatsoever resulting from the use or reliance on its contents.

Ricardo reference: ED14790

Contact:
Becca Johansen, 21 Prince Street, 1st Floor North, Bristol, BS1 4PH, UK

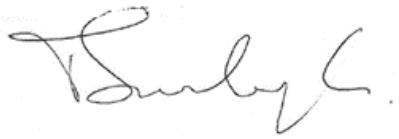
T: +44 (0) 1235 753 103
E: becca.johansen@ricardo.com

Author:
Becca Johansen, Brais Louro, Inge Kukla, Graham Pattle, Jodie Denmark, Chris Stone, Marina Diez, Conall Martin, Osmund Jenssen, Chris Hughes, Emily Butcher, Megan Griffiths (Ricardo)

Daniela Jeronimo Roque (Toxminds BvBA)

Approved by:
Tim Scarbrough

Signed



Date: March 2023

Ricardo is certified to ISO9001, ISO14001, ISO27001 and ISO45001.

Executive Summary

This is the summary report for the study commissioned by the European Chemicals Industry Council (Cefic) to assess the business impacts to the EU chemicals industry of selected actions from the Chemicals Strategy for Sustainability (CSS). This study feeds into Cefic's response to the EU Commission's CSS Impact Assessments. The actions assessed in the study were completed in two phases[1]:

Phase 1
- The addition of hazards to the CLP Regulation
- The extension of the Generic Risk Approach (GRA)
- The introduction of a Mixture Assessment Factor (MAF)

Phase 2
- The REACH registration of polymers
- A ban on exports subject to the GRA, REACH restriction or authorisation
- A qualitative assessment of the use of an essential use derogation in the context of the microplastics restriction under REACH[2]
- Implementing the PFAS restriction under REACH. (Issued as a separate report, i.e. not in this summary report)

This ex-ante assessment of selected policy options that are proposed within the CSS focusses on the business impacts such as compliance and operating costs incurred by the EU-27 chemical sector, and their responses to the regulatory changes (e.g., withdrawals from the market, substitution and/or reformulation). It is, therefore, considered a focussed assessment of business and business-driven economic impacts and so **costs and benefits to human health and the environment have not been considered**.

In this context, the assessment has been developed, to the extent possible, in accordance with the EC's Better Regulation Guidelines. The methodologies employed have been adapted based on the aforementioned scope and time available and building on the project team's practical experience in delivering Impact Assessments for private and public sector organisations.

To note, this study was performed prior to the completion of Commission Impact Assessments related to chemicals policy and so the assumptions and policy options carried forward for assessment are based on the understanding of the regulatory changes at the time of writing (Phase 1: January – November 2021, Phase 2: December – August 2022).

Policy Options and Key Assumptions

Table 8-1 presents the policy options that have been carried forward for quantitative assessment in this Study and the key assumptions as to their implementation. The assessment of the essential use derogation is a qualitative case study assessment.

Table 8-1 Policy options carried forward for assessment and key assumptions

Action	Concrete Policy Option Outlined in CSS	Assumed regulatory action	Assumed entry into force
Addition of Hazards to CLP	a) Establish hazard classes for endocrine disruption and apply to all legislation. b) Add new hazard classes to CLP addressing environmental toxicity, persistency, mobility and bioaccumulation (i.e. PBT/vPvB & PMT/vPvM)	New hazard classification: • Endocrine disruption (ED)	2023
		Hazard classifications brought across from REACH: • PBT/vPvB • PMT/vPvM	2023

[1] Phase 1 of this study ran from February to October 2021 and Phase 2 from January to August 2022.

[2] ECHA (2022) Registry of Restriction Intentions until outcome: Microplastics. Available from: https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

Action	Concrete Policy Option Outlined in CSS	Assumed regulatory action	Assumed entry into force
	c) Ensure that the CLP Regulation is the central piece for hazard classification and allows the Commission to initiate harmonised classifications	Hazard classification separated from established building blocks: • Immunotoxic • neurotoxic.	2032
Extension of GRA & Export Ban	a) Extend the generic approach to risk management (GRA) to ensure that consumer products do not contain CMR Cat. 1, ED, PBT/vPvB, and PMT/vPvM substances. In addition, immediately launch a comprehensive impact assessment to define the modalities and timing for extending the GRA to further harmful chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ. b) While the GRA is not in place, prioritise all the above-listed substances for restrictions for all uses and through grouping, instead of regulating them one by one. c) Extend the GRA to professional users under REACH d) Ensure EDs are banned in consumer products as soon as they are identified, except for essential uses. e) Hazardous chemicals banned or restricted in the European Union are not produced for export, including by amending relevant legislation if and as needed.	Export ban of all products currently restricted, authorised or prohibited in the EU	2023
		Extension of GRA to consumer and professional uses via REACH and sector specific legislation, and a ban on the export of these restricted products: • ED • PBT/vPvB • PMT/vPvM	2024
		Extension of GRA to consumer and professional uses via REACH and sector specific legislation, and a ban on the export of these restricted products: • Resp sens. Cat. 1, 1A & 1B • STOT RE/SE Cat. 1 & 2	2028
		Extension of GRA to consumer and professional uses via REACH and sector specific legislation, and a ban on the export of these restricted products: • Immunotoxic • Neurotoxic	2033
		Extend the GRA to consumer and professional uses via REACH Restriction (e.g. Article 68(2)) and sector specific legislation: • Skin sens. Cat. 1, 1A and 1B • CMR 2 • Aquatic chronic 1 and 2	2040
MAF	a) Introduction in REACH of a Mixture Assessment Factor (MAF) for the chemical safety assessment of substances	Introduction of a MAF of 10	2025
Polymer Registration	a) Add REACH Standard Information Requirements (SIR) for polymers requiring registration (PRR) b) Transition period for complying with polymer Registration requirements	Entry into force of REACH Registration requirements	2025
		Deadline for polymer manufacturers to perform testing and submit their registration dossiers	2032

For the assessment of impacts of the new hazards to CLP, the extension of the GRA and the export ban, three scenarios have been developed.

Box 1 Impact scenarios - CLP, GRA, export ban

Policy Scenario 1 considers the addition of hazard classes to CLP and extension of the GRA over a gradual implementation timetable, as outlined in Section 4.2.3 (and Figure 4 1). In this scenario, new hazard classes are introduced within the CLP framework. As substances are (re)classified according to CLP over time, they would also be affected by GRA restrictions/bans. These products would be withdrawn from the market unless they are substituted, reformulated and/or derogations are secured. In addition, a quarter of products that are only affected by CLP (that is, not covered by the GRA extension) would also face pressures to withdraw from the market or substitute/reformulate. In a context where both CLP and GRA changes are implemented simultaneously, this impact from CLP only is estimated to be relatively small.

Policy Scenario 2 assumes a faster, 5-year implementation timetable of the expected changes to the GRA and CLP. This includes the entry into force of all new hazard classes and all the extensions to the GRA. The faster implementation would require earlier and faster withdrawal of substances/ products from the market or their substitution and reformulation. Over time, however, the size of the EU chemicals market is estimated to converge to Scenario 1 levels.

Policy Scenario 3 considers that, especially if the policy changes are implemented quickly such as in Scenario 2, businesses may need time to adapt so they can bring substitutes and/or reformulated products to the market. Based on the available evidence , it has been assumed that companies may need, on average, around 5 years to adjust their operations and place their substitutes and/or reformulated products on the market. This would lead to larger turnover losses earlier on. Over time, sectoral turnover would also converge to the levels estimated in earlier scenarios.

Conclusions

Table presents a summary of the impacts of the selected CSS actions assessed in this Study. The actions that are assessed may be independent of each other (e.g. polymer registration) or directly linked to one another (e.g. additions of hazards to CLP and the extension of the GRA) (Figure 1-1)[3]. Even where actions are independent of each other, there will be a cumulative impact for companies within the chemicals industry where they are required to implement more than one of the CSS actions (See Box 2). It has not been possible to assess the cumulative impact of all actions within the scope of this study, due in part to the large number of participants and the variation in products that each company places on the market, which in turn dictates the legal requirements with which they must comply. However, it is acknowledged that the cumulative impact of the CSS will be higher than the impacts presented here.

Table 1-2 Summary of Impacts of each of the policies analysed for this study. Unless stated otherwise, losses are annualised per year against the baseline over the 2023-2040 period.

Policy Change	Scenarios	Turnover (first order effects)	Total GVA contribution (direct, indirect, induced)	Regulatory burden	Total employment contribution (direct, indirect, induced)
Addition of hazards to CLP & extension of	**Scenario 1** (Addition of hazard classes to CLP and extension of the GRA)	A loss of €47 billion	A loss of €40 billion	An additional burden of €434 million	77,000 fewer jobs, on average, when compared to the baseline in any given year

[3] To note, the impacts of polymer registration do not consider the additional impact as a result of further regulation, in particular the extension of the GRA.

Policy Change	Scenarios	Turnover (first order effects)	Total GVA contribution (direct, indirect, induced)	Regulatory burden	Total employment contribution (direct, indirect, induced)
	Scenario 2 (Faster, 5-year implementation timetable)	A loss of €67 billion	A loss of €57 billion	An additional burden of €518 million each year over the period	106,000 fewer jobs, on average, when compared to the baseline in any given year
	Scenario 3 (Faster implementation timetable with substitution/ reformulation difficulties)	A loss of €81 billion	A loss of €68 billion	An additional burden of €518 million each year with a delay	126,000 fewer jobs, on average, when compared to the baseline in any given year
Export ban *(partly overlapping with GRA and CLP)*	**Scenario 1** (Gradual implementation timetable)	A loss of €7.3 billion (10% loss by 2040)	A loss of €6.5 billion	An additional burden of €440 million	12,700 fewer jobs, on average, when compared to the baseline in any given year
	Scenario 2 (Faster, 5-year implementation timetable)	A loss of €9.5 billion (10% loss by 2040)	A loss of €8.3 billion	An additional burden of €530 million	15,700 fewer jobs, on average, when compared to the baseline in any given year
	Scenario 3 (Faster implementation timetable with substitution/ reformulation difficulties)	A loss of €11.0 billion (10% loss by 2040)	A loss of €9.5 billion	An additional burden of €560 million	17,700 fewer jobs, on average, when compared to the baseline in any given year
MAF	Substance 2	23-77 million euros lost	5-20 million euros lost ***(Only direct)***		50-150 jobs lost *(Only direct)*
	Substance 4	0.7-5.3 billion euros lost	0.2-1.4 billion euros lost *(Only direct)*		500-5,600 jobs lost *(Only direct)*
Polymer Registration	REACH SIR	A loss of €580 million	A loss of €3.2 billion	An additional annualised burden of €1.6 billion each year over a seven-year period	1,500 fewer jobs, on average, when compared to the baseline in any given year

Policy Change	Scenarios	Turnover (first order effects)	Total GVA contribution (direct, indirect, induced)	Regulatory burden	Total employment contribution (direct, indirect, induced)
	ECETOC Grouping and Testing	A loss of €660 million	A loss of €2.5 billion	An additional annualised burden of €1.2 billion each year over a seven-year period	1,700 fewer jobs, on average, when compared to the baseline in any given year

Qualitative conclusions on the application of the essential use concept to the REACH Restriction of intentionally added microplastics.

An essential use derogation could have resulted in a faster decision-making process, primarily due to the use of screening steps, for the applicable derogations considered in this restriction depending on how the concept is defined and applied to the stepwise derogation procedure. However, counter to this, there may be the requirement for an increase in the number of derogations to account for each use which may decrease the efficiency of the Restriction process. Derogations used to refine the scope of the restriction and based on no unacceptable risk are not applicable to the concept of essential use and are expected to remain alongside essential use derogations. The information burden placed on the essential use derogation applicant and the relevant Committees is expected to be comparable to the current REACH requirements although this burden will be refocused on to industry. Finally, the predictability and clarity of the process, if a stepwise approach is implemented and the criteria are defined clearly, could increase and thus benefit all stakeholders. Once more this possible benefit is highly dependent on a clear definition and communication of the essential use criteria.

CONTENTS

TABLE OF FIGURES

Table of Tables

Glossary

Abbreviation	Definition
ATP	Adaptations to Technical Progress
BPR	Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products
CAGR	Compound annual growth rate
CAPEX	Capital expenditure
Carc	Carcinogen
Cefic	European Chemical Industry Council
CLP	Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)
CLH	Harmonised Classification and Labelling
CLI	Classification and Labelling Inventory
CMR	Carcinogen, mutagen, reprotoxin
CSR	Chemical Safety Report
CSS	Chemicals Strategy for Sustainability
DU	Downstream Users
DUCC	Downstream Users of Chemicals Co-ordination Group
EC	European Commission
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
ED ENV	Endocrine disruption affecting the environment
ED HH	Endocrine disruption affecting human health
ELOC	Equivalent Level of Concern
EU	European Union
GCL	Generic concentration limit
GDP	Gross Domestic Product
GRA	Generic Approach to Risk Management (Generic Risk Approach)
GVA	Gross Value Added
LE	Large Enterprise
MSCA	Member State Competent Authority
Muta.	Mutagen
OPEX	Operating expenditure
OSH	Occupational Safety and Health
vPvB	Very persistent, very bioaccumulative
PBT	Persistent, Bioaccumulative and Toxic
PCN	Poison Centre Notifications
PFAS	Perfluoroalkyl chemicals

Abbreviation	Definition
PMT	Persistent, Mobile and Toxic
vPvM	Very Persistent and very mobile
PLC	Polymer of Low Concern
PP	Percentage point
PRR	Polymer requiring registration
R&D	Research and Development
RE	Repeated exposure
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
Repro.	Reprotoxin
RMM	Risk Management Measure
RMOA	Regulatory Management Option Analysis
SCCS	Scientific Committee for Consumer Safety
SCL	Specific concentration limit
SE	Single exposure
SDS	Safety data sheet
SME	Small & Medium Sized Enterprises
SoC	Substance of Concern
SRA	Specific Risk Assessment
STOT	Specific Target Organ Toxic
SVHC	Substances of very high concern
UNCED	UN Conference on Environment and Development
UN GHS	United Nations Global Harmonised System

1. INTRODUCTION

1.1 CONTEXT

Chemicals play a fundamental role in the functioning of our daily lives. They are the building blocks of the products we rely on every day, they contribute to food security, and in some cases even help protect our health. But they can have negative effects. As chemicals have wide dispersive uses and play such key roles in our daily lives there is a need to reduce harmful exposures, whilst also maintaining sustainable use. This is particularly true of chemicals which demonstrate hazardous properties such as those which cause cancer or gene mutation, affect the reproductive, endocrine or immune systems, are persistent, bioaccumulative, mobile or toxic to the environment. Exposure to these chemicals is a threat to human health and the environment, potentially contributing to climate change, biodiversity loss and environmental degradation.

In recognition of this, the European Union (EU) has regulated the exposure of humans and the environment to hazardous substances for over 50 years. This has led to the EU having one of the most comprehensive chemical regulatory frameworks in the world, comprising around 40 pieces of legislation. Two overarching pieces of the chemicals acquis, the REACH Regulation[4] and the Regulation on the Classification, Labelling and Packaging of hazardous substances (CLP)[5] introduced different regulatory management measures for substances, mixtures and, for REACH, articles with a range of hazardous properties, with more restrictive risk management for those which are deemed to be of highest concern. REACH aims to provide a high level of protection to human health and the environment, including the promotion of alternative methods for the assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

Collectively, this regulatory framework knowledge base informs regulatory actions in other regions and has become a model for the safe use of chemicals – reducing the risks to human health and the environment – whilst successfully maintaining the functioning of the single market.

1.2 THE EUROPEAN GREEN DEAL

The European Green Deal[6] was launched in December 2019 and set out the European Commission's (EC) commitment to tackling challenges such as atmospheric warming, climate change, environmental pollution and degradation. It is an integral part of the Commission's actions to implement the United Nation's 2030 Agenda and the Sustainable Development Goals. The Green Deal recognised that without good environmental health, human health suffers. And despite decades of regulatory action to prevent and/or reduce air, soil and water pollution, including the increased regulatory management of hazardous substances, more needs to be done to ensure a high level of protection to human health and the environment[7,8,9,10,11].

Among the themes of the Green Deal is the zero-pollution ambition for a toxic-free environment. To ensure the toxic-free environment ambition is met, the EU Green Deal stated that "*the Commission will present a **chemicals strategy for sustainability**… to protect citizens and the environment better against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives*". This strategy should bring all parties together, including industry, to increase health and environmental protection and global competitiveness through simplifying and strengthening the legal framework for chemicals.

---

[4] Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Available from https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32006R1907

[5] Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Available from: https://echa.europa.eu/regulations/clp/legislation

[6] European Commission (2019) The European Green Deal. COM(2019) 640 Final. Available from: https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF

[7] European Commission (2018) *Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions.* COM(2018) 116 final. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

[8] RPA et al (2017) Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation. Available from: https://op.europa.eu/en/publication-detail/-/publication/7e26e205-18f9-11e7-808e-01aa75ed71a1

[9] Amec Foster Wheeler et al (2017) Study supporting the Fitness Check on the most relevant chemicals legislation ("Fitness Check +")

[10] European Commission (2020) Commission Staff Working Document Fitness Check on endocrine disruptors. SWD(2020) 251 final. Available from: https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_on_Endocrines_disruptors.pdf

[11] Milieu et al (2017) *Study for the Strategy for a non-toxic environment of the 7th Environment Action programme.* Available from: https://ec.europa.eu/environment/chemicals/non-toxic/pdf/NTE%20main%20report%20final.pdf

1.3 THE CHEMICALS STRATEGY FOR SUSTAINABILITY

The Commission's Chemicals Strategy for Sustainability (CSS)[12], launched in October 2020, introduced a new long-term strategy for European chemicals policy. The CSS strives for a toxic-free environment, where chemicals are manufactured and used in a way that maximises their societal contribution but avoids causing harm to the environment or the population, now and in the future. The strategy contains around 80 action points which seek to simplify and strengthen the chemicals legislative framework to build a comprehensive knowledge base that can support evidence-based policymaking to facilitate the innovation of safe and sustainable chemicals, and ensure a greater level of protection of human health and the environment from hazardous chemicals.

To meet the aims of the CSS, innovation for green transition in the chemicals industry and its value chains is vital. But for this to be possible, the Commission has noted that EU chemicals policy must also evolve, responding more rapidly and effectively to the risks and challenges posed by hazardous chemicals. This should include the promotion of safe and sustainable use of chemicals, targeting those which have chronic effects on human health and the environment through substitution or phase out of the most harmful substances for which use is not deemed to be essential. Stimulating innovation will require both regulatory and non-regulatory incentives (e.g. financial) to ensure the EU chemicals industry remains competitive on a global scale. As the COVID-19 pandemic has shown, alongside the need to ensure a high level of protection to human health and the environment, there is also a need to strengthen the EU's open strategic autonomy with resilient value chains and diversify sustainable sourcing of chemicals that have essential uses for not only health, but also for achieving a climate-neutral and circular economy due to the complexity and globality of manufacturing and supply chains.[12]

1.4 STUDY AIMS AND SCOPE

This report is the summary report from the study commissioned by the European Chemicals Industry Council (Cefic) to **assess the business impacts to the EU chemicals industry of selected actions from the CSS**. This study feeds into Cefic's response to the EU Commission's CSS Impact Assessments. The actions assessed in the study were completed in two phases[13]:

Phase 1
- The addition of hazards to the CLP Regulation
- The extension of the Generic Risk Approach (GRA)
- The introduction of a Mixture Assessment Factor (MAF)

Phase 2
- The REACH registration of polymers
- A ban on exports subject to the GRA, REACH restriction or authorisation
- A qualitative assessment of the use of an essential use derogation in the context of the microplastics restriction under REACH[14]
  Implementing the PFAS restriction under REACH. *(Issued as a separate report, i.e. not in this summary report)*

The scope of this study is related to business impacts such as compliance and operating costs incurred by chemicals companies which place chemical products on the market (manufacture, import, formulation and sale) in the EU-27 and their responses to the regulatory changes (e.g., withdrawals from the market, substitution and/or reformulation).

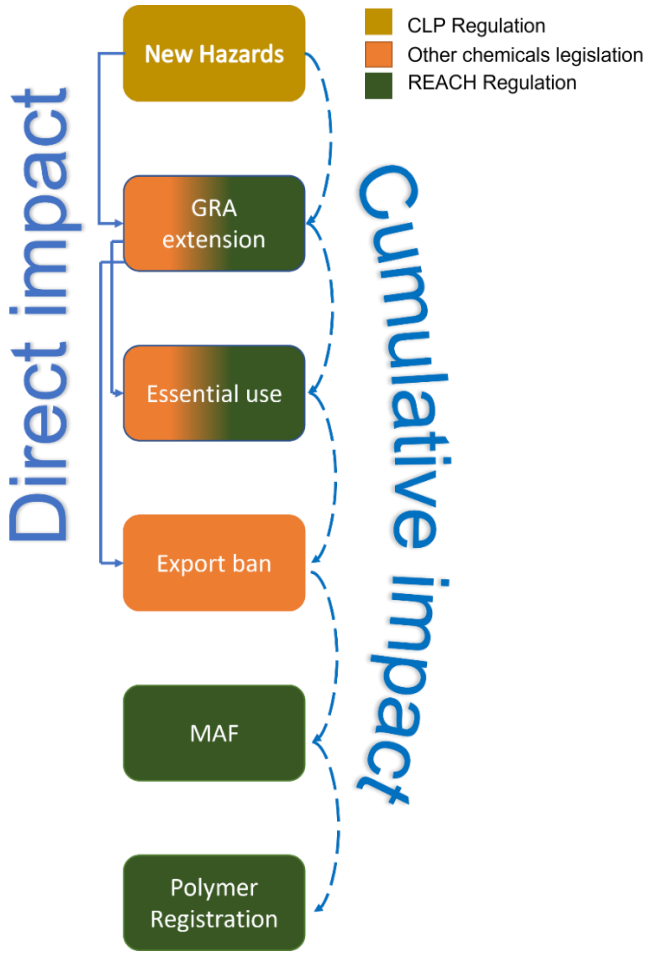
The actions that are assessed may be independent of each other (e.g. polymers registration) or directly linked to one another (e.g. additions of hazards to CLP and the extension of the GRA) (Figure 1-1). Even where actions are independent of each other, there will be a cumulative impact for companies within the chemicals industry where they are required to implement more than one of the CSS actions (See Box 2). It has not been possible to assess the cumulative impact of all actions within the scope of this study, due in part to the large number of participants and the variation in products that each company places on the market, which in turn dictates the legal requirements with which they must comply.

[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, COM(2020) 667 Final. Available from: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

[13] Phase 1 of this study ran from February to October 2021 and Phase 2 from January to August 2022.

[14] ECHA (2022) Registry of Restriction Intentions until outcome: Microplastics. Available from: https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

Figure 1-1 Depiction of the direct relationships between and cumulative effects of announced CSS regulations. (Source: Own elaboration)



Box 2 Example of cumulative impact

Company A is a manufacturer of industrial chemicals, including polymers, and a formulator of detergent, cosmetic and biocidal products. Some of the substances used in their products are classified in the future as endocrine disruptors.

Company A may need to comply with the addition of hazards to CLP, the extension of the GRA and the export ban, as well as the MAF and polymer registration requirements.

Company B may formulate paints and coatings only for professional and consumer use. Some of the substances used in their products are classified in the future as endocrine disruptors.

Company B may need to comply with the addition of hazards to CLP, the extension of the GRA and the export ban. As downstream users they may provide information to registrants under REACH but would not have their own registration requirements, excluding them from the application of the MAF and the polymer registration requirements.

To note, this study was performed prior to the completion of Commission Impact Assessments related to chemicals policy and so the assumptions and policy options carried forward for assessment are based on the understanding of the regulatory changes at the time of writing (Phase 1: January – November 2021, Phase 2: December – August 2022).

1.5 REPORT STRUCTURE

This summary report builds on the reports from Phase 1 and Phase 2. The Phase 1 report is available online[15]. The remainder of this summary report is structured as follows:

- Section 2: Methodology – ex ante Assessment of Business Impacts
- Section 3: Business context and baseline
- Section 4: Addition of hazards to the CLP Regulation, the extension of the GRA, and the ban on exports subject to the generic risk approach, REACH restriction or authorisation
- Section 5: Introduction of a MAF (Case Study)
- Section 6: REACH registration of polymers
- Section 7: Qualitative assessment of the essential use derogation in the context of the REACH microplastics restriction.
- Section 1: Overall conclusions.

[15] Ricardo (2021) Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability – Phase 1 Report. Available from: https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf

2. METHODOLOGY

The European Commission's Better Regulation Guidelines and Toolbox[16] defines ex ante impact assessment as the process of "*gathering and analysing evidence to support policymaking*", that is, providing evidence that could inform policy decisions at the EU level ahead of implementing a policy action.

This ex-ante assessment of selected policy options that are already proposed within the CSS focusses on considering how the EU-27 chemicals sector may be affected and any potential knock-on effects on the EU-27 economy. It is, therefore, considered a focussed assessment of business and business-driven economic impacts and so **costs and benefits to human health and the environment have not been considered**. It is expected that the impacts to human health and the environment will be considered in the European Commission's Impact Assessments related to the CSS.

In this context, the assessment has been developed, to the extent possible, in accordance with the EC's Better Regulation Guidelines. The methodologies employed have been adapted based on the aforementioned scope and time available and building on the project team's practical experience in delivering Impact Assessments for private and public sector organisations.

The methodologies are summarised in six steps.

Step 1: Define and characterise the baseline scenario against which to assess options. The study considered how the status quo would likely evolve, including key economic and sectoral indicators at the EU-27 economy and chemicals sector level, without any further policy changes in the EU Chemicals legislation. This work was inspired by the latest Better Regulation Guidelines, and particularly drawing from Tool #16 (how to identify policy options) and Tool #60 (baselines)

Step 2: Specify the policy options considered. The CSS was reviewed to produce a longlist of (80+) action points that the EC could take forward. This longlist was screened to identify which are likely to be most impactful, following an approach inspired by Tool #16 (how to identify policy options) of the Better Regulation Guidelines. This process resulted in a selection of policy options of: proposed changes to the GRA, the addition of new hazards to the CLP Regulation and the introduction of MAF (Phase 1), polymer registration requirement under REACH, the ban on exports subject to the GRA, REACH restriction and authorisation, the essential use derogation, and the PFAS restriction (Phase 2). To assess these options, further development was required, based on informed assumptions and expert input, such as an implementation timetable and others.

Step 3: Map and screen the business and economic impact categories. A longlist of twelve economic impacts was developed and screened, based on Tool #18 (identification of impacts) of the Better Regulation Toolbox. From these, five business and economic impact categories were identified as likely to be significant for a more in-depth assessment. Across these impact categories, different types of economic costs and benefits were considered based on Tool #56 (typology of costs and benefits) of the Better Regulation Toolbox. Social and environmental impacts and, therefore, any indirect economic impacts driven by these, were not in scope of this exercise.

Step 4: Stakeholder consultation and evidence gathering. Stakeholder engagement fed into all the aforementioned steps. The consultation activities and data analysis were based on Tool #54 (analysing data and informing policymaking) and other tools of the Better Regulation Toolbox, as pertinent. These activities included targeted consultations with business stakeholders for each policy option assessed, and for the polymers assessment, an additional consultation with Contract Research Organisations (CROs) to identify costs of testing and laboratory capacity. In addition, the consultation activities were complemented by a rapid literature review.

Step 5: Assess the business and economic impacts of the policy options. Business and economic impacts were assessed by employing analytical models and methods based on Tools #58 (EU standard cost model), #61 (simulation models), #63 (cost-benefit analysis) and other tools of the Better Regulation Toolbox. These analytical approaches included: statistical techniques for the development of a counterfactual; the quantification of policy effects based on evidence collected

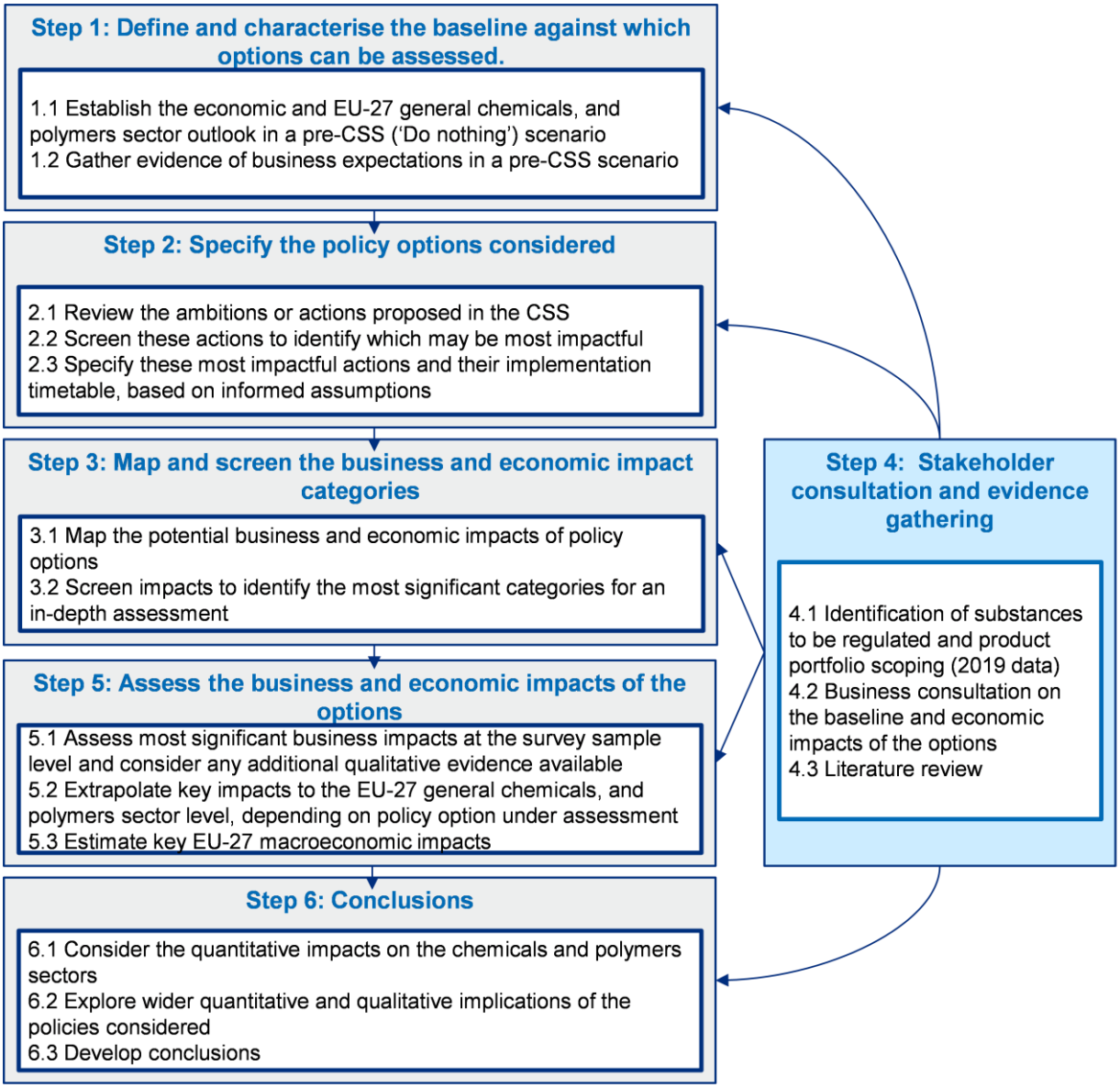
[16] European Commission (2017) *Better regulation: guidelines and toolbox.* Available from: Better regulation: guidelines and toolbox | European Commission (europa.eu)

through a business survey; and statistical techniques for the extrapolation of impacts from the survey sample to the EU-27 chemicals and polymers sectors.

Step 6: Conclusions. This quantitative and qualitative evidence on business and economic impacts was employed to present the implications of the selected policy options from the CSS. These implications have also provided a basis to develop insights and/or conclusions for consideration by policymakers as they continue to concretise the options and ambitions set out within the CSS.

These methodological steps are also depicted in Figure 2-1. The assessment of the essential use concept followed a qualitative approach focusing on the predicted advantages and disadvantages of replacing the current substance[17] specific restriction derogations used in REACH with the sole derogation for essential uses. The assessment compared the current REACH restriction derogation process with the proposed implementation of the essential use concept generically to map the main similarities and differences. To precisely compare the approaches, a case study on the development of derogations and exemptions for the REACH restriction on intentionally added microplastics has been conducted and analysed.

Figure 2-1 The methodological steps underpinning this assessment of business and economic impacts



[17] Substances to be regulated are defined in this study as substances which meet the classification criteria for: carcinogenic, mutagenic, reprotoxic (CMR) cat. 1A/1B/2; endocrine disruptor (ED) for human health and the environment; persistent, bioaccumulative, toxic (PBT); very persistent very bioaccumulative (vPvB); persistent, mobile, toxic (PMT); very persistent, very mobile (vPvM); respiratory sensitisation cat. 1/1A/1B; specific target organ toxicity repeated exposure (STOT RE) cat. 1/2; specific target organ toxicity single exposure (STOT SE) cat.1/2; immunotoxic; neurotoxic; skin sensitisation cat. 1/1A/1B; aquatic chronic cat. 1/2.

The limitations of the methodology and the implications these have on the analysis are described in Table .

Table 2-1 Limitations of the methodology and implications

Limitations	Implications
Uncertainty of policy proposals. The actions outlined in the CSS remain considerations of a strategy and are subject to ordinary legislative procedure. No formal decision has been made on the implementation of these policy proposals by the Commission and discussion is ongoing.	Policy details are not yet clear, and assumptions have been required. As discussions are ongoing, the assumptions made in this assessment may not accurately reflect the regulatory changes that will ultimately enter into force. The assessment carried out and its outputs are highly dependent on these assumptions and, therefore, reflect the same level of uncertainty.
There are known unknowns. These include: • How technological progress may affect the EU chemicals sector and whether and how this would interact with the impacts of legislation. • How grouping of chemicals will affect the speed of regulation	An estimate of how grouping may expediate regulatory action has been included in the weighting of hazard classifications and polymers requiring registration. This is based on limited evidence and the grouping of chemicals results in much faster regulatory management.
Data available is in some cases limited and biased to large firms. Limited historical evidence of relevance and data gathered through the consultation exercises is restricted by the sample of respondents and their understanding and assessment of how the policies considered may affect their operations. The sample comprises a disproportionate number of large firms (41 large vs 6 SME in the survey for the restriction on exports; 48 large vs 17 SME in the survey for polymers registration), while they are a minority in the sector (800 out of 28,000 in the overall chemicals sector)[18]. However, the sample covers two-thirds of the sector's turnover, thus being considered overall representative of the sector's average.	It has been necessary to rely on consulting businesses to gather evidence of the potential actions they may take as a response to the legislative proposals and the associated costs and benefits. The breakdown of this sample (e.g. SMEs versus large enterprises) and any outputs considered by firm size will need to be treated with caution and caveated accordingly.
Complexity of actions taken in response to regulatory change. The extent to which these impacts affect sub-sectors and businesses, and how these businesses may respond, will vary, including whether businesses will discontinue, reformulate or substitute the use and manufacture of certain products. Any of these actions will incur transitional and/or recurring costs when compared to the baseline.	An informed simplification of the impact pathway, based on the project team expertise, was introduced, with inherent limitations. Due to the number and complexity of business affected, assumptions have had to be made on the actions that will be taken in response to the regulatory changes (e.g. substitution, reformulation, product loss).

[18] Large company is defined as having a staff headcount of ≥250 and a turnover of >€50 million or a balance sheet total of >€43 million. Source available from: https://ec.europa.eu/growth/smes/sme-definition_en
As such there is variance in the size of large companies, with a mix of multinationals and EU-centric companies.

Stakeholder consultation and evidence gathering

The consultation activities and data analysis carried out in this study were based on Tool #54 (and others) of the Better Regulation Toolbox. These activities included two targeted consultations in Phase 1 with business stakeholders and a separate consultation with registration consortia members only for the MAF module, and separate targeted consultations with business stakeholders for the module on the export ban and the module on polymer registration in Phase 2. For the polymers module an additional consultation was carried out with Contract Research Organisations (CROs) to gather data on the costs of testing and laboratory capacity. In addition, the consultation activities were complemented by a rapid literature review.

The consultation activities covered:

Table 2-2 Consultation scope

Phase 1	Phase 2

CLP and GRA modules
• Consultation with manufacturers, importers, formulators and downstream users
  ○ Part 1 - The identification of substances to be regulated and product portfolio scoping
  ○ Part 2 - The consideration of business and economic impacts of changes to the GRA and CLP
	Polymer registration module
	• Consultation with polymer manufacturers and importers:
	  ○ Part 1 - The identification of polymers placed on the market in the EU, including those which meet the criteria for polymer of low concern (PLC), polymer precursor, and the number of polymer requiring registration (PRR) groups based on two grouping strategies (see Figure 6-1) .
	  ○ Part 2 - The consideration of business and economic impacts of the introduction of polymer registration under REACH.
	• Consultation with CROs – the identification of costs of testing and laboratory capacity.

MAF module
• Consortia of the four selected substances were engaged as part of this project.
  ○ The consideration of direct business responses in the EU-27 and associated costs and benefits over at least 10 years from the adoption of MAF.
  ○ The consideration of business and economic impacts of the MAF
  ○ Interviews with a range of the survey respondents were also carried out to test and challenge their responses and ensure they would be interpreted effectively.
	Export ban module
	• Consultation with chemicals manufacturers and formulators with an extra-EU export portfolio
	  ○ The consideration of business and economic impacts of the proposed ban on exports subject to the GRA, REACH restriction or authorisation.

3. BUSINESS CONTEXT AND BASELINE

This section outlines the main economic statistics for the EU-27 chemicals sector and presents the picture of its current business context and trends. Baseline projections are presented for selected economic indicators, which are taken as reference throughout the analysis of business impacts. Differences between large businesses and SMEs are considered where possible and applicable.

3.1 SECTORAL SCOPE AND CONTEXT

European chemicals companies carry out a wide range of activities and develop a wide variety of products for daily use: fertilisers and pesticides, plastics, paints, soap and detergents, fragrances, cosmetic products, textiles and other fibres, etc. To encompass this breadth, the scope of the chemical industry that is used in this Study is Nomenclature of Economic Activities (NACE) Rev. 2 Code C20, which is defined as follows:

> "*This division includes the transformation of organic and inorganic raw materials by a chemical process and the formation of products. It distinguishes the production of basic chemicals that constitute the first industry group from the production of intermediate and end products produced by further processing of basic chemicals that make up the remaining industry classes*."[19]

This sector comprises more than 28,000 businesses and employs more than one million people in the EU-27. In 2019, these companies manufactured chemical products and/or placed products in the EU-27 market worth over €570 billion per year[20], of which under a quarter, or €140 billion per year, represents the sector's Gross Value Added (GVA) to the European economy (i.e., its direct contribution to Gross Domestic Product (GDP)). This is significant; in fact, the sector is the fifth largest manufacturing sector in the EU-27 by GVA, representing around 7.2% of the manufacturing industry's value added and around 1% of the EU-27 GDP[21].

Further, 800 Large businesses, or c.3% of the total, generate around 70% of sectoral output and employ more than 600,000 workers. The rest is generated by more than 27,000 Small and Medium Enterprises (SMEs) that employ more than 400,000 workers[22].

Extra-EU exports of the European chemicals sector amount to €95 billion and represent 11% of total world chemicals exports[23] in 2019. Over the last decade, European chemicals' exports have grown steadily, and the trade balance remains positive with a 15% surplus of total extra-EU trade of chemical products, highlighting the sector's competitiveness. Nevertheless, the European share of the global chemicals market has declined over the same period, with other countries experiencing faster growth, especially China, and capturing an increasing share of the global chemicals market.[24]

A 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU chemical industry[25] suggests that the regulatory burden affecting the sector represents over 2% of their turnover[26]. This

---

[19] Eurostat, (2008). *Statistical classification of economic activities in the European Community*. NACE Rev. 2. Eurostat Methodologies and Working papers. Available from: dd5443f5-b886-40e4-920d-9df03590ff91 (europa.eu)

[20] All monetary figures are expressed in 2020 constant euros.

[21] Eurostat (2022), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 03/2022].

[22] European Commission (2019) Commission Staff Working Document Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries SWD/2019/199 final/2. Available from: EUR-Lex - 52019SC0199 - EN - EUR-Lex (europa.eu). All employment figures are expressed in FTE units.

[23] Eurostat (2021), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 09/2021] and Cefic (2021), *Facts and Figures*. [online] Available from: 2021 Facts and Figures of the European Chemical Industry - cefic.org [Accessed 09/2021]

[24] The study team acknowledges that recent data on international trade of chemicals suggests that the EU has become a net importer of chemicals at least between March and July 2022. These data come from an alternative measure of trade at the level of the EU-27 that considers a larger statistical population (see https://ec.europa.eu/eurostat/cache/metadata/en/ext_tec_sims.htm for a methodological explanation), and following the Classification of Products by Activity (CPA) (online data code DS-057009). Historically, the EU-27 had been a net exporter of chemicals as indicated by the EXT_TEC01 dataset that was used for this study, so it would not be unreasonable to assume that this result will appear eventually in the EXT_TEC01 dataset should this reversal of trends be maintained. In this latter dataset, the latest data available is 2020 as of December 2022.

[25] Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission), Technopolis Group, VVA. (2016). *Cumulative Cost Assessment for the EU Chemical Industry*. European Commission. Available from: https://op.europa.eu/en/publication-detail/-/publication/8eb1b47a-ee94-11e6-ad7c-01aa75ed71a1/language-en

[26] The cumulative cost assessment study assessed costs across the EU-28 between 2004 and 2014, so it should be understood as an indicative reference or approximation, given that this present study considers the burden within the EU-27 for the period 2008-2018 and projects this forward as part of the baseline.

also represents 30% of the industry's Gross Operating Surplus, which suggests that this burden plays a role in shaping the sector's profitability. The existing chemicals-specific legislation in the EU is estimated to generate around a third of this total burden.

Changes to the classification of substances also tend to require additional investments and administrative activity from businesses, that is, yield regulatory burden. While the cumulative cost assessment study excludes regulatory costs from changes in the classification of substances, they are included in this assessment.

Finally, regulatory burden varies across subsectors, reflecting differences in product groups and their production chains. SMEs can also incur comparatively higher costs in some cases, due to non-linearities with respect to production volume.

3.1.1 Business Context specific to the polymers sector

Polymers are widely used chemical products across a variety of sectors and applications such as medical, aerospace, packaging, automotive, construction, and electrical appliances sector. The scope of the polymers sector used for this assessment is more specific than that referred to in Section 3.1 and corresponds to NACE Rev. 2 Codes C20.16 and C20.17 which are defined as follows:

Box 3 NACE Rev. 2 code definitions

C20.16 Manufacture of plastics in primary forms: "*This class includes: manufacture of plastics in primary forms: polymers, including those of ethylene, propylene, styrene, vinyl chloride, vinyl acetate and acrylics, polyamides, phenolic and epoxide resins and polyurethanes, alkyd and polyester resins and polyethers, silicones, ion-exchangers based on polymers and the manufacture of cellulose*".

C20.17 Manufacture of synthetic rubber in primary forms: "*This class includes manufacture of synthetic rubber in primary forms: synthetic rubber, factice, manufacture of mixtures of synthetic rubber and natural rubber or rubber-like gums (e.g. balata)*".[27]

The sector comprises almost 2,500 business and employs more than 136,000 people in the EU-27. In 2019, these companies manufactured polymers and/or placed products on the EU-27 market worth €102 billion per year[28], of which almost a fifth, or €19 billion per year, represented the sector's GVA to the European economy (i.e., its direct contribution to GDP).

Around 100 large businesses, or around 4% of the total, generate around 80% of sectoral output and employ almost 100,000 workers. The rest is generated by more than 2,000 SMEs that employ around 36,000 workers[29].

For polymer manufacturers, the regulatory burden affecting the sector was estimated to be 0.4% of their turnover in the 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU chemical industry[30,31]. This also represents 4.5% of the industry's Gross Operating Surplus as of 2019, which suggests that this burden plays a limited role in shaping the polymers sector's profitability. The lower regulatory burden may in part be due to the current lack of registration obligations for polymers under REACH.

[27] Ibid footnote 19

[28] All monetary figures are expressed in 2020 constant euros.

[29] Ibid footnote 22

[30] Ibid footnote 25

[31] The study assessed costs across the EU-28 between 2004 and 2014, so it should be understood as an indicative reference or approximation, given that this considers the burden within the EU-27 for the period 2008-2018 and projects this forward as part of the baseline.

3.2 HISTORICAL TRENDS AND BASELINE PROJECTIONS

Over the last 10 years, the turnover or revenue of the European chemicals sector has grown 2.2% per year, on average. Recently, however, the COVID-19 pandemic has had an impact on the operations of the European chemicals sector. In 2020, the pandemic resulted in a contraction of sectoral revenue and productive output that is estimated at -7%[32]. The contraction in European economies experienced during the pandemic is expected to be rapidly overcome, according to European Commission's estimations of GDP recovery[33], with sector revenue estimated to grow 6% in 2021 and 4% in 2022. Similarly, the Gross Value Added of the chemicals sector is projected to grow at 6.1% and 3.6% in 2021 and 2022, respectively. Thereafter, the sector is estimated to continue on a long-term growth trend.

Further, the contribution of the European Chemicals sector to the global market has declined according to Eurostat, at least from 2014, although probably from as early as 2008 based on data from the EU-27 and the United Kingdom[34]. Most recently, over the last five years, the EU-27 sector's contribution to world exports has declined from 13% to 11%.

With regard to the European polymer sector (which is, in itself, a part of the chemicals sector), its turnover (revenue) has increased by 0.4% each year on average during the last ten years. The pandemic is estimated to have resulted in a -9% reduction in this sector's revenue and productive output in 2020, with sector revenue predicted to climb 4% both in 2021 and 2022, and 3% in 2023. The polymers sector's GVA is estimated to increase by 5% and 6% in 2021 and 2022, respectively, and 4% in 2023. Following that, its turnover is expected to grow at a moderate pace, 0.3% CAGR on average until 2040.

Over the coming decades, these key trends are assumed to continue if no further regulatory action is taken. This is the baseline or 'Do nothing' scenario, i.e., a counterfactual case where the CSS would not be implemented. These baseline scenario projections and trends are considered for seven indicators or themes:

- Turnover, including from exports
- Gross Value Added
- Intermediate consumption and operating costs
- Capital expenditure
- Research and Development
- Regulatory burden of the EU-27 chemicals legislation
- Employment

All baseline projections are estimated based on publicly available data of the EU chemicals sector and also at the level at the EU polymers sector for the module focussed on polymers.

It should be noted that the baseline developed for this study was determined before the outbreak of war in Ukraine. It is acknowledged that geo-political crises have an impact on trade and market dynamics and so due to resource availability and increasing energy prices, growth of the chemicals industry may not follow the projections included in this report.

[32] Ricardo own estimations from econometric regressions relating the output of the EU-27 chemicals sector to EU-27 GDP and population.

[33] European Commission. (2021). *Summer 2021 Economic Forecast*. Available from: https://ec.europa.eu/info/business-economy-euro/economic-performance-and-forecasts/economic-forecasts/summer-2021-economic-forecast_en

[34] Cefic (2021), *Facts and Figures*. [online] Cefic Available from: 2021 Facts and Figures of the European Chemical Industry - cefic.org [Accessed 09/2021]

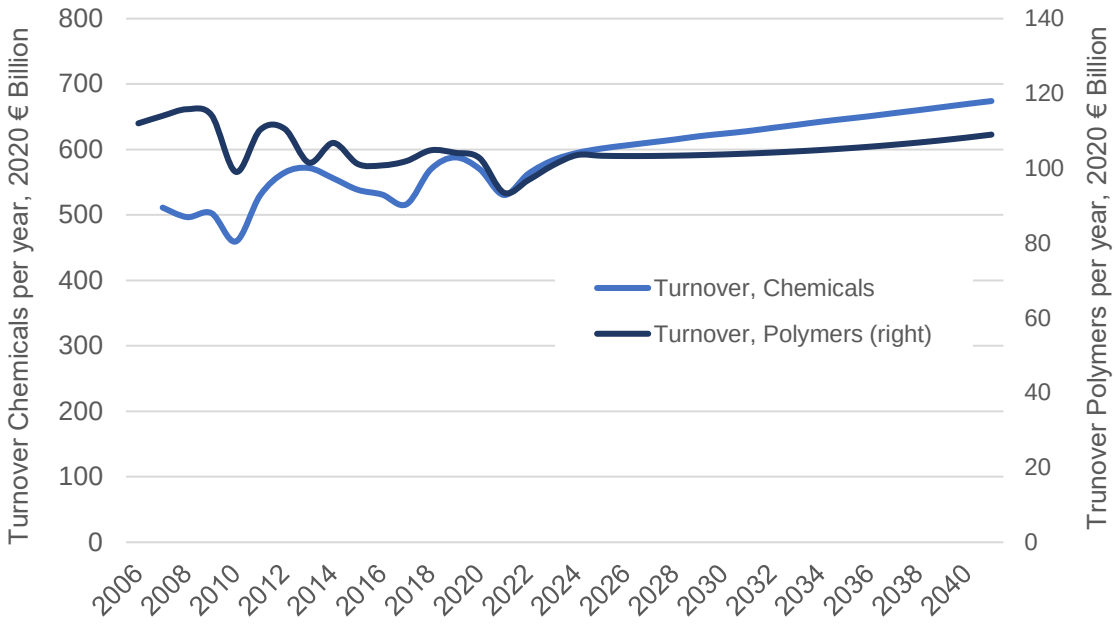
3.2.1 Turnover of the EU-27 chemicals sector

The European chemical sector's turnover is projected to grow at a Compound Annual Growth Rate (CAGR) of 0.7% over the next 20 years (turnover from polymers is estimated to grow at a CAGR of 0.3%) and is depicted in Figure 3-1 below, with turnover for the chemicals sector on the left-hand axis. This estimate is based on the current and expected growth of the European economy, the overall business context and the policy baseline. These projections align with the growth that may be expected from a mature industry, sustained and stable but moderate, amounting to a cumulative growth of 13% from 2023 to 2040 (5.3% cumulative growth for polymers).

Over the last decade, large enterprises have driven the growth of the EU chemicals sector[35]. Their turnover has grown at a CAGR of 2% during this period, or a cumulative growth of 21%. SMEs have experienced a more moderate annual growth rate of 0.2%, or a cumulative growth of 2% over the period. A similar albeit stronger trend is observed in the polymers sector (represented in the right-hand axis), with the contribution of SMEs having decreased over time in the last decade (-4.6% annually).

As a result, the share of turnover from large enterprises has increased over time and reached 69% of total sectoral output (80% in the case of the polymers subsector). However, in the last 13 years, there has been some volatility in the contribution of large businesses versus SMEs to sectoral sales. Therefore, based on the broad historical trends, it is possible that the share of turnover generated by large firms will continue to increase.

Figure 3-1 Total turnover of the EU-27 chemicals sector (left axis) and the polymers subsector (right axis).

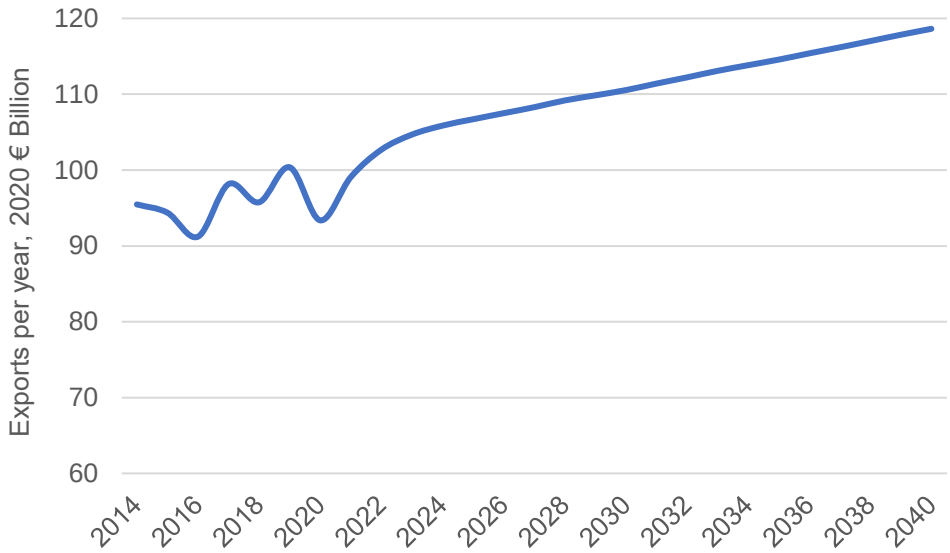


Source: Ricardo analysis for year 2020 onwards, based on Eurostat data for years 2008 to 2019.

In line with the expected evolution of the chemicals sector's overall turnover, exports are expected to grow at a CAGR of 0.7% over the next two decades. The projection of exports for the chemicals sector is shown in Figure 3-2 below (data not available at the level of the polymers sector).

[35] Ibid footnote 21

Figure 3-2 Turnover from the exports of the EU-27 chemicals sector.



Source: Ricardo analysis for year 2020 onwards, based on Eurostat data for years 2008 to 2019. Note y axis does not start at zero.

3.2.2 Value added of the EU-27 chemicals sector

The Gross Value Added (GVA) of the chemicals sector, defined as the value of output or production minus intermediate consumption of goods and services (gross, i.e., before taxes), refers to its contribution to Gross Domestic Product (GDP).

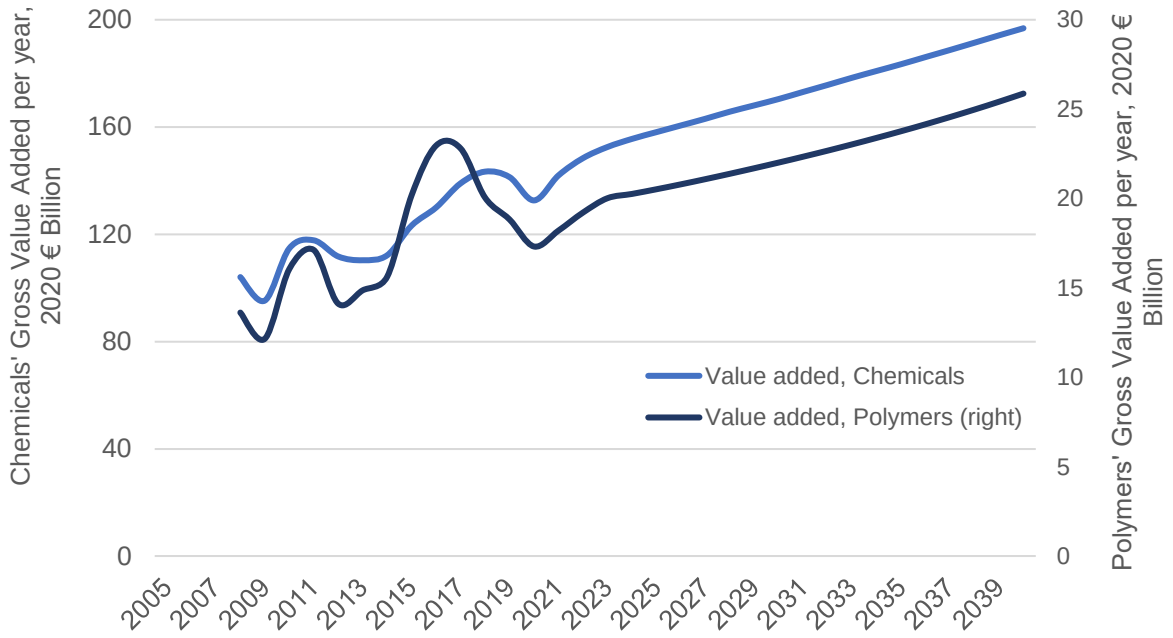
The GVA of the sector amounted to around €140 billion in 2019, equivalent to over a quarter of its economic output (20% in the case of polymers, with €19 billion). This has increased steadily over the last decade at a CAGR of 4% (slightly more for polymers), which is twice as fast as the sector's output growth. Two trends have potentially contributed to this:

- Intermediate costs have grown at a slower pace than output (1.5% vs 2.1% per year; 0.1 % vs. 0.9 % per year respectively in the case of polymers) over the last decade, whilst the chemicals sector reduced its energy intensity by an estimated 22%[36], and this trend is also expected to have taken place for the polymers subsector. This implies a reduction of intermediate costs in relative terms (e.g., per unit of turnover).
- The sector's expenditure on R&D has grown more rapidly than output (2.7% vs 2.1%, and 2.4% vs 0.9% respectively in the case of polymers). The sector's innovation has likely translated into higher value creation.

These trends were experienced by both large and smaller enterprises; however, large firms appear to have contributed relatively more to sectoral GVA growth.

[36] Ibid footnote 34

Figure 3-3 Gross value added of the chemicals sector (left axis) and the polymers subsector (right axis) in the EU-27.



Source: Ricardo analysis for year 2020 onwards, based on Eurostat data for years 2008 to 2019.

3.2.3 Intermediate consumption, including operating costs of the EU-27 chemicals industry

The intermediate consumption of the European chemicals industry refers to the value of the industry's demand of "goods and services consumed as inputs by a process of production"[37]. This represents a significant proportion of operating costs of the industry as well as its interconnectedness with the local (and international) economy and ability to drive activity through the supply chain.

There is historical data available for this indicator at the EU-27 chemicals sector level, which has been used to produce baseline projections. These projections offer a proxy for the evolution of operational costs, whilst it is acknowledged that intermediate consumption excludes the costs of employment and other, less significant day-to-day costs. When required, this gap has been addressed by estimating and adding employment costs to intermediate consumption for a sector level estimate of operating costs.

The intermediate consumption has grown at a CAGR of 1.5% in the last decade (0.1% in the case of polymers). Therefore, this means that intermediate consumption per unit of revenue has declined. A similar trend is assumed for operating costs. Efforts towards an energy transition are partly driving this net cost reduction, with a 22% reduction in energy intensity in the chemicals sector from 2008[38].

This trend is assumed to continue, as showcased in Figure 3-4 below. Further and significant improvements in energy efficiency are still expected through to 2050[39], partly driven by the ongoing efforts from industry and European and national level policy ambitions, such as the recent European Green Deal[40]. This transition will be costly and require both rising operating as well as capital expenditures, but in the net and although uncertain, it is expected to drive a similar level of growth to the baseline, further reducing operating cost per unit of revenue.

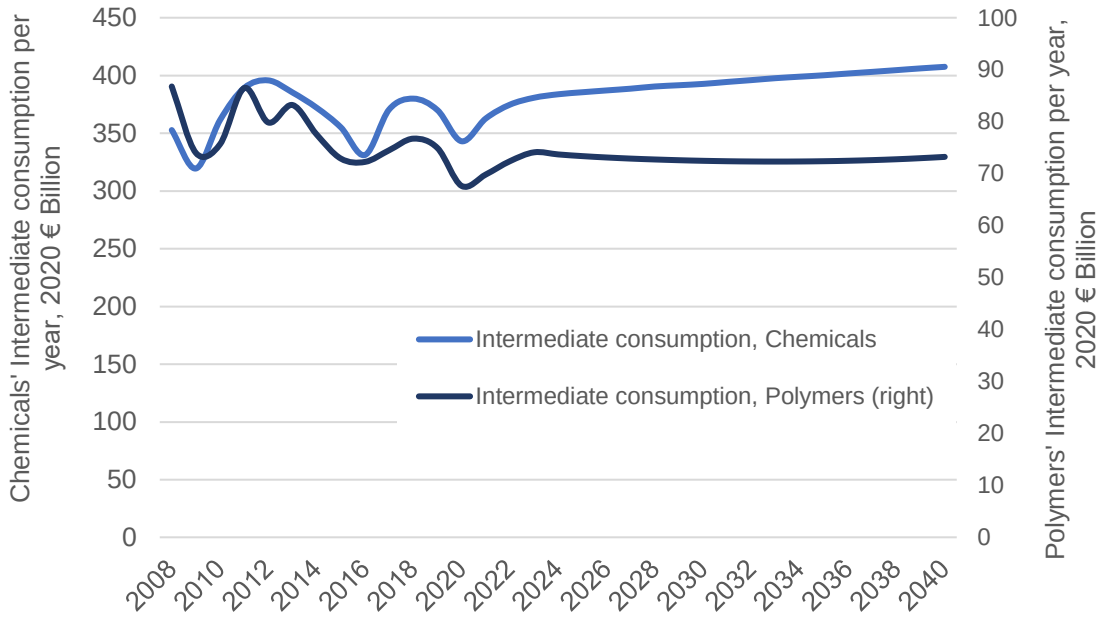
[37] Eurostat, (2021). *Glossary* [Online] Eurostat. Available from: Glossary: Intermediate consumption - Statistics Explained (europa.eu)

[38] Ibid footnote 34

[39] European Commission (2021) Commission Staff Working Document: For a resilient, innovative, sustainable and digital energy-intensive industries ecosystem: Scenarios for a transition pathway. (SWD(2021)277 final). Available from: https://ec.europa.eu/docsroom/documents/47059/attachments/1/translations/en/renditions/native

[40] European Commission (2019) *Communication from the Commission to the European Parliament, the European Council, The Council, The European Economic and Social Committee and the Committee of the Regions: The European Green Deal*. COM(2019) 640 Final. Available from: https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF

Figure 3-4 Intermediate consumption of the EU-27 chemicals sector (left axis) and the polymers subsector (right axis).



Source: Ricardo analysis for year 2020 onwards, based on Eurostat data for years 2008 to 2019.

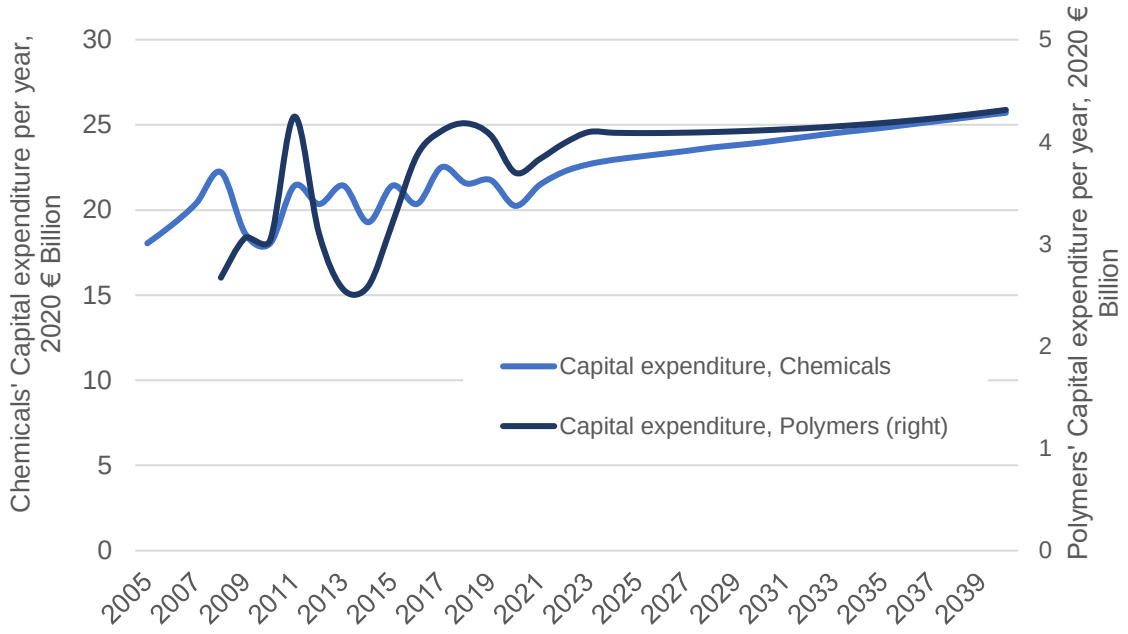
3.2.4 Capital expenditure activity in the EU-27 chemicals sector

Capital expenditure by the chemicals sector has generally grown in the last decade. The investment based in the EU-27 has grown at a CAGR of 1.6% from 2009 to 2019 (2.9% in the case of polymers). This growth is slower than that of China and, to a lesser extent, the North American economies. This has meant that the EU-27's share of global capital investment has declined over time, from a share close to 30% in the early 2000s to a current level of around 11% in the past four years.

For the next two decades, the observed growth trend in capital expenditure is assumed to continue, slightly above the estimated turnover growth (1.0% growth vs 0.7%; 0.3% in the case of polymers). These estimates are based on historical trends. More recent developments, such as the increasing focus in moving faster towards climate neutrality and other demands on the sector, may require faster growth in the capital expenditure of the EU chemicals sector.

Despite these limitations, as well as a limited basis to justify increased growth in investment that would be more in line with the most recent history in the polymer sector, it is deemed that these projections offer a reasonable baseline against which to assess the impacts of the policy changes considered in this study. Historical evidence and future projections of capital expenditure by the EU-27 chemicals sector (left-hand axis) and polymers subsector (right-hand axis) are shown in Figure 3-5 below. Estimations capture the potential trend, albeit these are uncertain, and it is possible that future Capex will continue to show significant volatility, especially in the case of polymers, surpassing and dropping below the estimated trend of overall annual increases.

Figure 3-5 Capital expenditure in the EU-27 chemicals sector (left axis) and the polymers subsector (right axis).



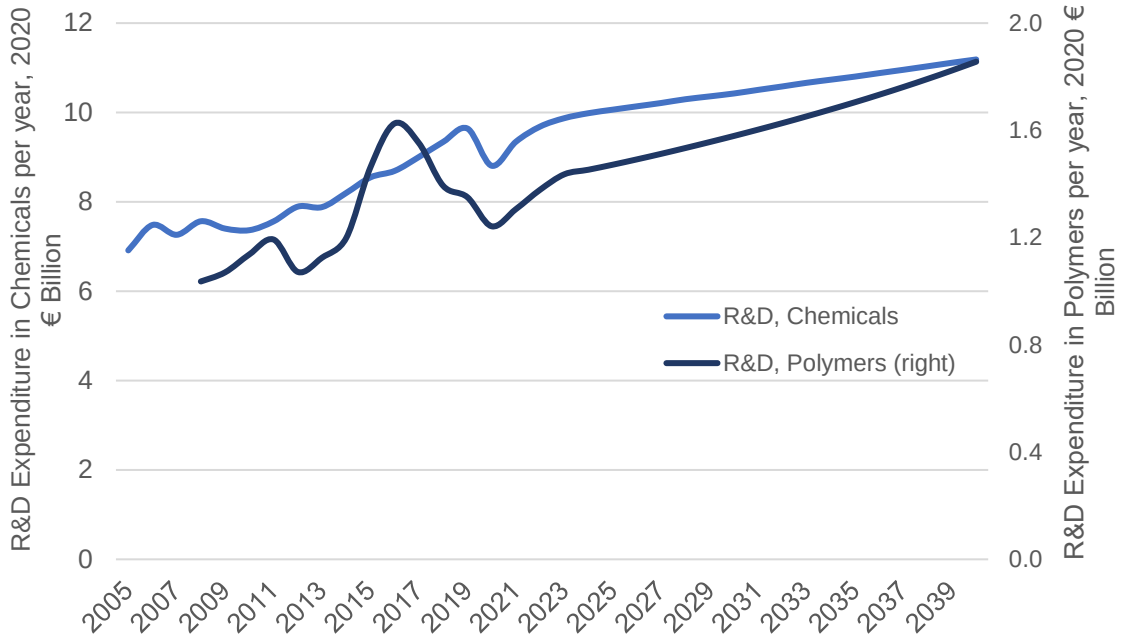
Source: Ricardo analysis for year 2020 onwards, based on Eurostat data for years 2008 to 2019.

3.2.5 Research and Development in the EU-27 chemicals sector

Expenditure in R&D by the European chemicals sector has grown at a relatively fast pace when compared to its turnover. Future R&D trends will depend upon the recovery from the global pandemic crisis and general economic growth.

Based on the evidence available, as shown in Figure 3-6 below, it is estimated that R&D expenditure will grow at least in line with the sectoral turnover (left-hand axis), or 0.7% per year on average (faster in the case of polymers –see right-hand axis, with 1.5% per year on average). It is possible that recent historical trends of relatively fast-paced growth will continue; however, this is uncertain.

Figure 3-6 R&D expenditure of the chemicals sector (left axis) and the polymers subsector (right axis) in the EU-27.



Source: Ricardo analysis for year 2020 onwards, based on Eurostat data for years 2008 to 2019.

In addition to this expenditure in the EU-27, some chemical companies also invest and/or develop some or all of their R&D activities outside of the EU. A survey of over 100 businesses in the sector suggests that over half of the respondents develop all of their R&D activities in the EU-27, around a third develop the majority (>50%) of their R&D activities in the EU, and 15% develop less than 50% of their activities in Europe. While the expenditure outside of the EU-27 does not have the same footprint on the European economy, the outputs and outcomes of these investments (i.e., innovation) would still have an impact on the sector's production and value added in the EU.

In the particular case of polymers, responses to a survey of 65 companies in the polymers industry show that over 40% develop all of their R&D operations in the EU-27, approximately a third develop the majority (>50%) of their R&D activities in the EU, and 20% develop less than 50% of their activities in Europe.

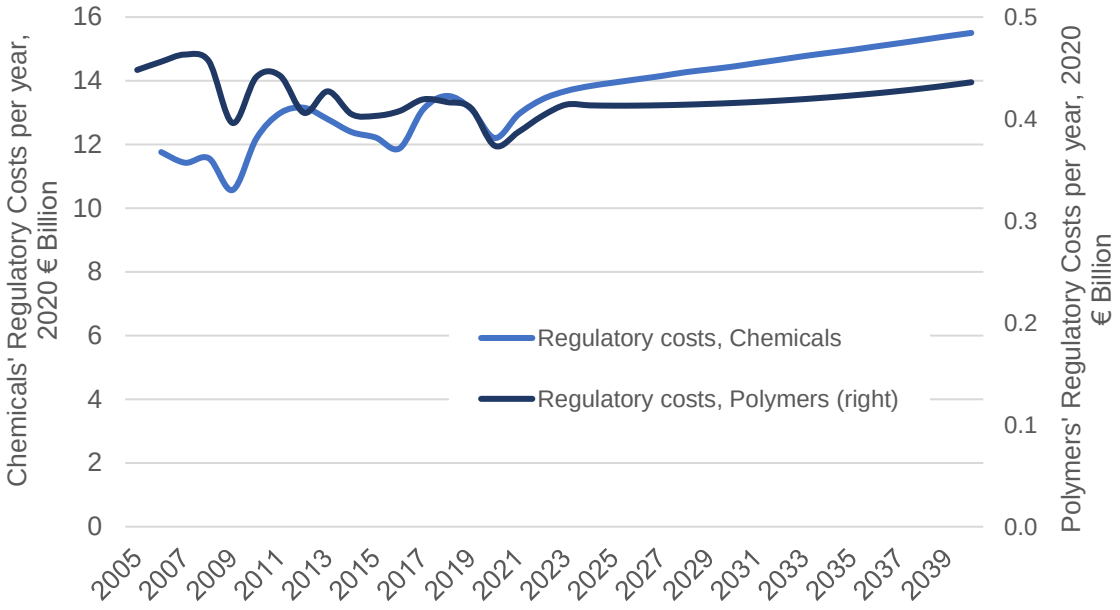
3.2.6 Regulatory burden of the EU-27 chemicals sector

As noted earlier, the 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU chemical industry[41] suggests that the regulatory burden affecting the sector represents over 2% of their turnover, also reported in more recent study by Cefic[42]. The same study estimates regulatory burden for the plastics (or polymers) sector to be 0.4% of their turnover. Many of the regulatory burden categories shown below for the overall chemicals sector are not applicable to the polymers manufacturing sector, hence the lower regulatory burden.

In the baseline scenario, it is assumed that the level of burden as a percentage of turnover will remain as estimated by this study. As shown in Figure 3-7 below, this would imply that annual regulatory burden in 2019 amounted to around €13 billion in the chemicals sector (left axis), and €0.4 billion in the case of polymers (right axis), and this burden would be likely to grow over time in line with the estimated increase in sectoral operations and associated turnover.

[41] Ibid footnote 25
[42] Ibid footnote 34

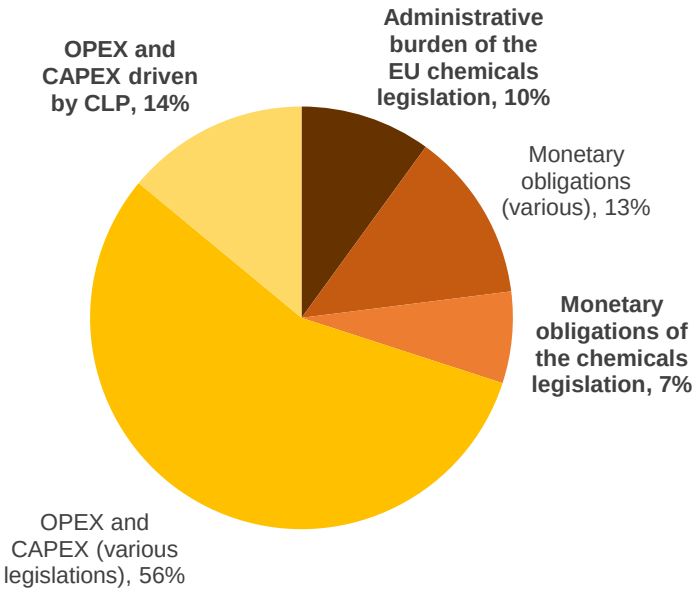
Figure 3-7 Total regulatory costs of the chemicals sector (left axis) and the polymers subsector (right axis) in the EU-27.



Source: Ricardo analysis based on Eurostat data and the Cumulative Cost Assessment study[43]

These regulatory burden estimates capture the administrative costs generated by EU chemicals legislation, which includes the cost of the preparation and submission of information for registrations, the issue of permits, and information for product users (e.g., labels), and represents 10% of the total burden, as shown in Figure 3-8 below. Monetary obligations represent another 20%, of which 7 percentage points (pp) stem from the chemicals legislation package alone; OPEX and CAPEX represent the remaining 70%, of which those generated by the chemicals legislation, and mainly driven by CLP, represent 14% of total regulatory burden.

Figure 3-8 Composition of the regulatory burden affecting the chemicals sector in the EU-27 (Regulatory burden of the categories in bold are driven by EU chemicals legislation only)



Source: Cumulative Cost Assessment study[44] (Own elaboration)

[43] Ibid footnote 25
[44] Ibid footnote 25

Further, as an illustration of how this regulatory burden may affect the industry, a recent study by ECHA[45] highlights the extent to which CAPEX and OPEX increase as a result of EU chemicals legislation. "For instance, some companies have incurred over €50 million one-off costs in the substitution of diglyme, trichloroethylene, chromium trioxide, DEHP, DBP and HBCDD. These substances were also reported to have one of the highest annual costs, as for most of them, the annual costs are over €10 million".

3.2.7 Employment

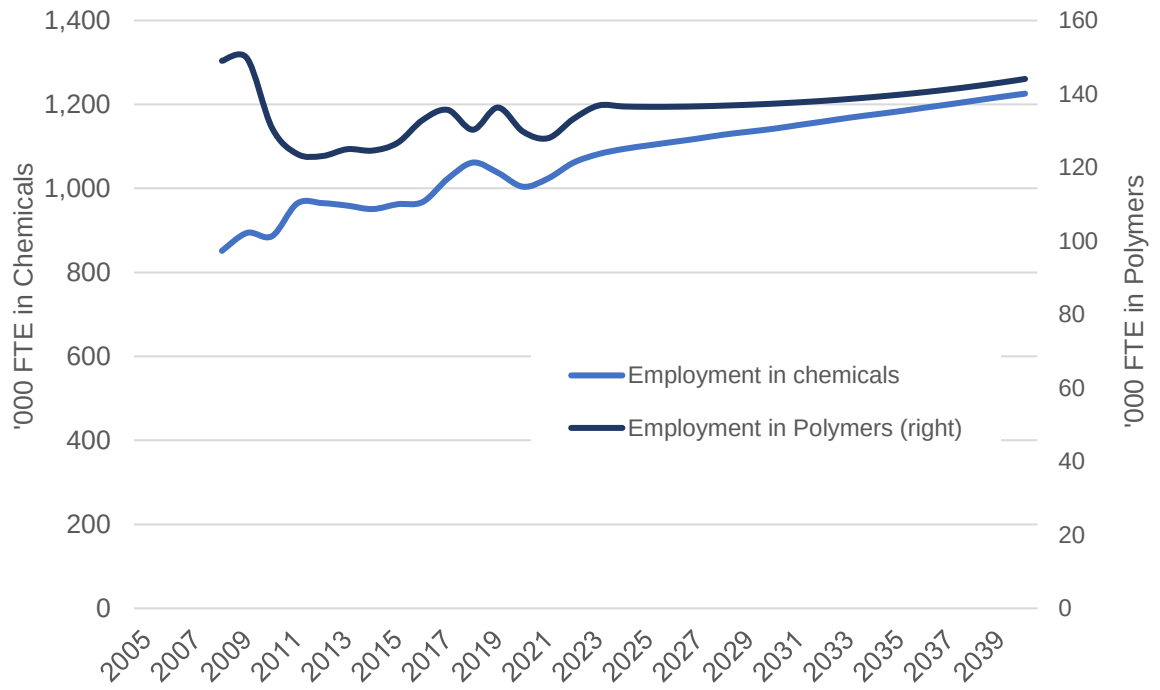
The chemicals industry is characterised by the employment of highly qualified professionals, who are remunerated accordingly. Employment compensation in the chemicals industry is among the highest, behind only petroleum refining and pharmaceuticals. Within the wider chemicals sector, salaries in polymer manufacturing are above average.

As the EU-27 chemicals sector continues to expand in the future, this is likely to be complemented by an increase in labour demand. However, this relationship between the sector's output and employment has some particularities:

- In the short run, employment has historically been less volatile than sectoral output or production. For example, when output drops, employment declines with lower intensity and, usually, with a time lag. The adjustment in employment is also likely to spread over a longer period than in output. This is driven by the relative rigidity of the labour market in the EU-27 when compared to the market of goods and services, meaning that production is more easily and immediately adjusted than employment.
- In the long run, however, employment and production are assumed to follow similar trends, unless any significant technological and/or production process changes substantially affect this relationship between production and employment. This is uncertain and has not been considered in the baseline projections below.

Based on these considerations and trend analysis, employment is assumed to grow broadly in line with turnover, 0.7% per year on average (and 0.3% in the case of polymers), with the exception of a slower contraction in 2020 and a smoother recovery thereafter. This is shown below in Figure 3-9.

Figure 3-9 Employment in the EU-27 chemicals sector (left axis) and the polymers subsector (right axis). FTE: Full-time equivalent employees.



Source: Ricardo analysis for year 2020 onwards, based on Eurostat data for years 2008 to 2019.

[45] ECHA (2020) *"Impacts of REACH restriction and authorisation on substitution in the EU"*; DOI: 10.2823/39789

Large enterprises, even though they are only 3% of all firms in the chemicals sector, represent more than 60% of the total chemicals sector employment or over 600,000 employees. This share is assumed to be, at least, maintained in the baseline scenario.

4. ADDITION OF HAZARDS TO CLP, EXTENSION OF THE GRA AND BAN ON EXPORTS SUBJECT TO THE GRA, REACH RESTRICTION AND AUTHORISATION

This section provides an overview of the business impacts of the addition of hazards to the CLP Regulation and the extension of the GRA. There is a direct link between the addition of hazards and the extension of the GRA and so these impacts have been assessed together and presented jointly. The section is set out as follows:

- Section 4.1 – context
- Section 4.2 – policy options considered
- Section 4.3 – business impacts of the addition of hazards to the CLP Regulation and the extension of the GRA.
- Section 4.4 - business impacts of the ban on exports subject to the GRA, REACH restriction and authorisation.

4.1 CONTEXT

This section provides insight into the context surrounding the policy options considered in this assessment, including hazard classification and communication and risk management approaches.

4.1.1 Policy Context Specific to Hazard Communication

Hazard communication in the EU is regulated by the CLP Regulation through harmonised criteria for classification of substances and mixtures, and rules on labelling and packaging for hazardous substances and mixtures. CLP is based on the United Nations' Globally Harmonised System (UN GHS)[46]. The aim of the CLP Regulation is to ensure a high-level of protection to human health and the environment, whilst maintaining the free movement of substances, mixtures and articles. The CLP Regulation[47] meets this aim through:

- Harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures in line with the GHS building blocks;
- Providing an obligation for:
    - Manufacturers, importers and downstream users to classify substances and mixtures placed on the market;
    - Suppliers to label and package substances and mixtures that are placed on the market;
    - Manufacturers, producers of articles and importers to classify those substances that are not placed on the market but are subject to registration or notification under REACH;
- Establishing a list of substances with their harmonised classifications and labelling elements where these are not submitted to ECHA as part of REACH;
- Establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements.

4.1.2 Policy Context Specific to Current Risk Management Approaches

In the EU chemicals acquis, traditionally there have been two main approaches to risk management; one based on specific risk assessment (SRA) and the other based on generic risk considerations, also known as the generic approach to risk management or generic risk approach (GRA)[48] . Both risk assessment methods aim to ensure a high level of protection to human health and the environment, but they differ in their approach to achieve this goal. The GRA is utilised by several pieces of EU chemicals legislation and adopts the

[46] ECHA. (n.d.) *Understanding CLP* Available from: https://echa.europa.eu/regulations/clp/understanding-clp

[47] *Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.* The Official Journal of the European Union. Available from: https://echa.europa.eu/regulations/clp/legislation

[48] European Commission (2019) *Commission Staff Working Document Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries SWD/2019/199 final/2. Available from:* EUR-Lex - 52019SC0199 - EN - EUR-Lex (europa.eu)

precautionary principle. In the EU, the GRA is applied to certain REACH Restrictions, in particular under Article 68(2) of REACH, and through sector specific legislation.

The publication of the CSS included use of the terminology '*generic approach to risk management*', hereby referred to as GRA, and the SRA. Their definitions are shown in Box 2.

Box 4 Overview of the GRA and SRA, taken from the CSS

*A **'generic approach to risk management'** is an automatic trigger of pre-determined risk management measures (e.g. packaging requirements, restrictions, bans, etc.) based on the hazardous properties of the chemical and generic considerations of their exposure (e.g. widespread uses, uses in products destined to children, difficult to control exposure). It is applied in a number of pieces of legislation on the basis of specific considerations (e.g. characteristics of the hazard, vulnerability of certain population groups, non-controllable or widespread exposure).*

***'Specific risk assessments'** consider the hazard, the use of the substances and related specific exposure scenarios for humans and the environment, and risk management measures are triggered based on their outcomes'*[49]

EU chemicals legislation incorporates the specific risk approach in two main ways[50]:

- **Leading to REACH Authorisation:** The responsibility to prove the safety of the substance lies with the manufacturers or users of the substance. In this instance the substance is presumed 'guilty until proven innocent', once the safety of the substance has been confirmed and in the absence of a suitable alternative, it will be added to a list of authorised substances for specific uses. To note, inclusion of a substance in the List of Substances Subject to Authorisation (Annex XIV) may be deemed to be use of the GRA, whereas the process of Authorising specific uses is SRA.
- **Leading to Restriction:** The assessment is carried out by Member State Competent Authorities. Substances which have been identified as hazardous must be assessed via a specific risk assessment to determine the appropriate outcome. The substance may be banned or there may be a need to limit the substance concentration or restrict certain uses.

4.2 POLICY OPTIONS CONSIDERED

Whilst the CSS does not include detailed guidance on the proposed actions around CLP and the GRA, it does indicate expected actions that will be taken by the Commission. These actions have been carried forward as policy options for this assessment.

The screening of policy options from the CSS reinforced the selection of the following actions:

- Addition of hazards to the CLP Regulation
- Extension of the GRA.

These policy options, that is, the changes to CLP and GRA, are described below, followed by more detail and the expected timings for implementation in Table . Assumptions have been developed by the study team and Cefic and are based on a review of publicly available literature.

4.2.1 Changes to the CLP

New hazard classes (ED, PBT, vPvB, PMT, vPvM, Immunotoxicants and Neurotoxicants) will be included as part of CLP. The direct impact of these changes is primarily an increase in administrative or compliance activities, including update of labels, SDS, renotification to the C&L inventory and to Poison Centres and update of registration dossiers, that take the form of additional costs.

It is expected that the inclusion of new hazard classes in CLP will not result in an immediate re-harmonisation of classifications to the new hazard classes. The process will take place gradually, following the harmonised classification and labelling (CLH) processes and subject to the existing or newly generated evidence necessary

[49] Ibid footnote 12
[50] Ibid footnote 9

to support classification, as well as resource availability from authorities. This is a key assumption for the assessment of business impacts reported in this study.

These reclassifications could also have indirect impacts, for example, companies may consider product discontinuation or substitution (e.g., as seen for CMR2 in fast moving consumer goods, fluorinated substances in food packaging in Denmark). This is driven by non-legislative pressures such as the SIN-list, pressure from retailers, expectations from consumers and professionals, ecolabelling schemes, etc. The extent to which products will be discontinued or substituted/reformulated [through this indirect channel] as a result of CLP changes only has not been investigated directly, although an assumption based on expert input has been considered.

4.2.2 Changes to the GRA

According to the CSS, the GRA will result in the banning of certain hazard classes in consumer and professional uses. Once substances have been through the process of harmonised classification, substances, mixtures and possibly articles containing the CLP-classified substances will be affected by generic restrictions.

The impact will occur as a result of implementation through REACH and sectoral legislation. **To note, the GRA does not include REACH Authorisation (nor SVHC listing), it is employed via REACH Restriction (including an extension of Article 68(2)) and sector specific legislation.**

4.2.3 Assumed implementation timeline

Table summarises the policy options brought forward for assessment and the assumed implementation timeline.

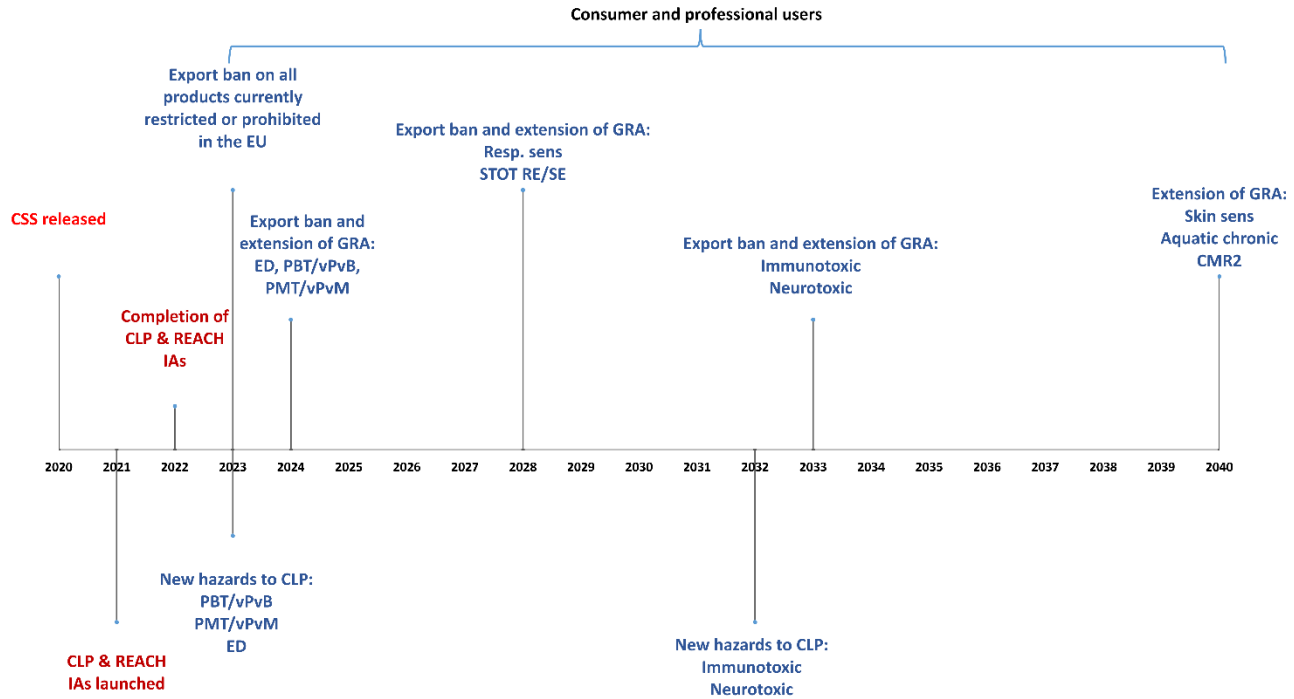
Table 4-1 Policy options and assumptions used in the analysis for the addition of new hazard classes to CLP, extension of the GRA, and introduction of an export ban.

Action	Concrete Policy Option Outlined in CSS	Assumed regulatory action	Assumed entry into force
Addition of Hazards to CLP	a) Propose to establish legally binding hazard identification of endocrine disruptors, based on the definition of the WHO, building on criteria already developed for pesticides and biocides, and apply it across all legislation b) Propose new hazard classes and criteria in the CLP Regulation to fully address environmental toxicity, persistency, mobility and bioaccumulation c) Ensure that the CLP Regulation is the central piece for hazard classification and allows the Commission to initiate harmonised classifications	New hazard classification: • Endocrine disruption (ED)	2023
		Hazard classifications brought across from REACH: • persistent, bioaccumulative, toxic (PBT) • very persistent, very bioaccumulative (vPvB) • persistent, mobile, toxic (PMT) • very persistent, very mobile (vPvM)	2023
		Hazard classification separated from established building blocks: • Immunotoxic • neurotoxic.	2032
Extension of GRA & Export Ban	a) Extend the generic approach to risk management to ensure that consumer products – including, among other things, food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textiles - do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative. In addition, immediately launch a comprehensive impact assessment to	Export ban of all products currently restricted, authorised or prohibited in the EU	2023
		Extension of GRA to consumer and professional uses via REACH (e.g. Article 68(2)) and sector specific legislation, and a ban on the export of these restricted products: • ED • PBT/vPvB • PMT/vPvM	2024

Action	Concrete Policy Option Outlined in CSS	Assumed regulatory action	Assumed entry into force
	define the modalities and timing for extending the same generic approach, with regard to consumer products, to further harmful chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ. b) While the generic approach to risk management is not in place, prioritise all the above-listed substances for restrictions for all uses and through grouping, instead of regulating them one by one. c) Extend to professional users under REACH the level of protection granted to consumers d) Ensure that endocrine disruptors are banned in consumer products as soon as they are identified, allowing their use only where it is proven to be essential for society e) Hazardous chemicals banned or restricted in the European Union are not produced for export, including by amending relevant legislation if and as needed		
		Extension of GRA to consumer and professional uses via REACH (e.g. Article 68(2)) and sector specific legislation, and a ban on the export of these restricted products: • Resp sens. Cat. 1, 1A & 1B • STOT RE/SE Cat. 1 & 2	2028
		Extension of GRA to consumer and professional uses via REACH (e.g. Article 68(2)) and sector specific legislation, and a ban on the export of these restricted products: • Immunotoxic • Neurotoxic	2033
		Extend the generic risk approach to consumer and professional uses via REACH Restriction (e.g. Article 68(2)) and sector specific legislation: • Skin sens. Cat. 1, 1A and 1B • CMR 2 • Aquatic chronic 1 and 2	2040

Figure 4-1 presents the indicative policy timeline that has been assumed in our assessment of the impacts.

Figure 4-1 Assumed Timeline of Implementation



This timeline is based on the Action Plan in the Annex to the CSS, updated based on expert judgement to reflect discussion in the CARACAL, and the need for Commission Impact Assessments to be completed. The extension of the GRA to respiratory sensitisers, STOT RE/SE substances is assumed to occur in 2028, whilst the extension to immunotoxicants and neurotoxicants is assumed to occur in 2033. This is based on the assumption that the Commission shall phase the extension of the GRA based on the severity of hazard in order to allow for businesses to respond to the regulatory change. It is also assumed that the extension to immunotoxic and neurotoxic substances shall be slower than that for respiratory sensitisers and STOT RE/SE substances as there is a need to introduce new hazard classes which are not currently building blocks of the UN GHS. This requires agreement of parties at UN level before changes can be actioned in CLP.

These, and other assumptions, offer a workable and reasonable approach to assessing impacts of the policy options considered, albeit with limitations.

Table 4-2 Extension of the Generic Approach to Risk Management (consumers and professionals)

Extension Phase	Year	Hazard Class
1	2024	ED PBT/vPvB PMT/vPvM
2.1	2028	Resp sens. Cat. 1, 1A & 1B STOT RE/SE Cat. 1 & 2
2.2	2033	Immunotoxic Neurotoxic
3	2040	CMR Cat. 2 Skin sens. Cat. 1, 1A & 1B Aquatic chronic 1 and 2

4.3 BUSINESS IMPACTS OF THE ADDITION OF HAZARDS TO THE CLP REGULATION AND THE EXTENSION OF THE GRA.

The changes to the GRA and CLP considered in this study are generally expected to restrict the manufacturing and use of products and/or increase their costs of production. This will in turn have significant and potentially negative impacts on the evolution of the EU-27 chemicals market and its competitiveness despite a robust and mitigative response from the sector.

4.3.1 Portfolio of products that may be affected by changes to the GRA and CLP

Participating chemical companies were firstly consulted to identify and quantify the products they manufacture and sell that are likely to be affected by the policy options considered. To do this, members had to identify all products that they placed on the market in the EU-27 or manufactured for export that contained any of the substances included in the List of Substances to be Regulated. The List of Substances to be Regulated, was created based on CSS actions to act as the basis for the screening of product portfolios. The list was developed through the use of publicly available information on hazardous substances and contained over 12,000 substances which either currently or may in the future be classified as:

- Carcinogen (C) category 1A, 1B, 2;
- Mutagen (M) category 1A, 1B, 2;
- Toxic for reproduction (R) category 1A, 1B, 2;
- Persistent, bioaccumulative, toxic (PBT);
- Very persistent, very bioaccumulative (vPvB);
- Persistent, mobile, toxic (PMT);
- Very persistent, very mobile (vPvM);

- Endocrine disruptor (ED) for human health or the environment;
- Respiratory sensitiser category 1, 1A, 1B;
- Specific Target Organ Toxicity – repeated exposure (STOT RE) category 1, 2;
- Specific Target Organ Toxicity – Single Exposure (STOT SE) category 1, 2;
- Immunotoxic;
- Neurotoxic;
- Skin sensitiser category 1, 1A, 2;
- Aquatic chronic category 1, 2.

The hazard classifications of concern were selected based on the Commission definition of substances of concern (SoC) in the CSS (Box 3). Certain hazard classes were excluded as they were deemed unlikely to be included in the extension of the GRA (aquatic chronic cat. 3 and 4).

Box 5 European Commission definition of Substances of Concern included in the CSS

"…*primarily those related to circular economy, substances having a chronic effect for human health or the environment (Candidate list in REACH and Annex VI to the CLP Regulation) but also those which hamper recycling for safe and high quality secondary raw materials*"[51]

Around 100 chemical companies were asked to consider the products in their 2019 product portfolio that could be affected, if the policy options would be fully adopted with immediate effect (i.e., in 2023). In this case, the size of the potentially affected product portfolio was estimated to be around 43% of sectoral turnover, which would be equivalent to more than €240 billion of the 2019 market.

This estimate captures all products (industrial, professional and consumer use products) that contain the new hazard classifications for CLP (ED, PBT, vPvB, PMT, vPvM, immunotoxic and neurotoxic) and assumes all potential future classifications[52] (F1/F2) are in place.

F1 and F2 refers to substances that are not currently recognised as substances to be regulated in the EU but might be recognized as such in the future, depending on several uncertainties including the implementation of the European Commission's EU Chemical Strategy for Sustainability (CSS). Specifically:

- **"F1"** refers to substances undergoing, or having undergone, formal evaluation outside the EU of their hazard properties; and substances which, according to existing scientific evidence, could fall under a hazard classification.
- **"F2"** refers to substances for which there are indications that they may fulfil the criteria for a hazard classification, but where data are not sufficient to draw conclusions on hazard in the EU. Such indications include international evaluations, third party publications and hazard screening information (e.g. ready biodegradability, log Kow).

It also captures all the restrictions defined as GRA for professional or consumer use products, but does not consider potential implications of SVHC listing and subsequent Annex XIV inclusion of these substances that may apply in addition to the GRA (e.g. for industrial uses).

Available evidence, past experience of CLP and study team expert opinion suggests, however, that the policy options may not be implemented immediately (i.e., in 2023) nor in full. Rather, it is most likely that the Commission implements specific regulatory actions over time. At present, some of the expected classification criteria remain uncertain.

Therefore, this estimate was overlayed with a policy implementation timeline and policy uncertainties were taken into account, using weightings to account for the possibility that some substances identified in the list of substances to be regulated would not meet the classification criteria or there may be a lack of evidence to fulfil

[51] Ibid footnote 12

[52] CMR 1A/1B, PMT, vPvM, PBT, vPvB, ED, STOT SE/RE 1/2, Respiratory Sensitisers, Immunotox, Neurotox.

the classification criteria. Moreover, these adjustments also account for the potential grouping of substances based on the approach taken by ECHA that was presented in the Integrated Regulatory Strategy[53].

After these adjustments are applied, the size of products in scope of being affected by the policy changes by 2040 would be lower and **around 28% of the estimated sectoral turnover, which would be equivalent to more than €150 billion of the 2019 market**.

These estimates could be considered unlikely upper bounds for the potential reduction of the EU chemicals market in the event that the proposed changes to CLP and the GRA are adopted in full and the EU chemicals industry does not adapt, where possible, to mitigate these impacts.

4.3.2 Expected business response

The evidence collected confirms that businesses would respond robustly to these policy changes. To the best of their knowledge, businesses will substitute and/or reformulate around a third of their products that face pressures for withdrawal from the changes to the GRA, although this will depend on a positive market uptake. To a lesser extent, around 5%-10% of the products affected by the changes to the GRA could also benefit from successful derogations.

In addition, a quarter of the products that may only be affected by changes to CLP are expected to face indirect pressures to withdraw their products from the market. These businesses will also be able to substitute and/or reformulate some of their products to mitigate any potential market losses.

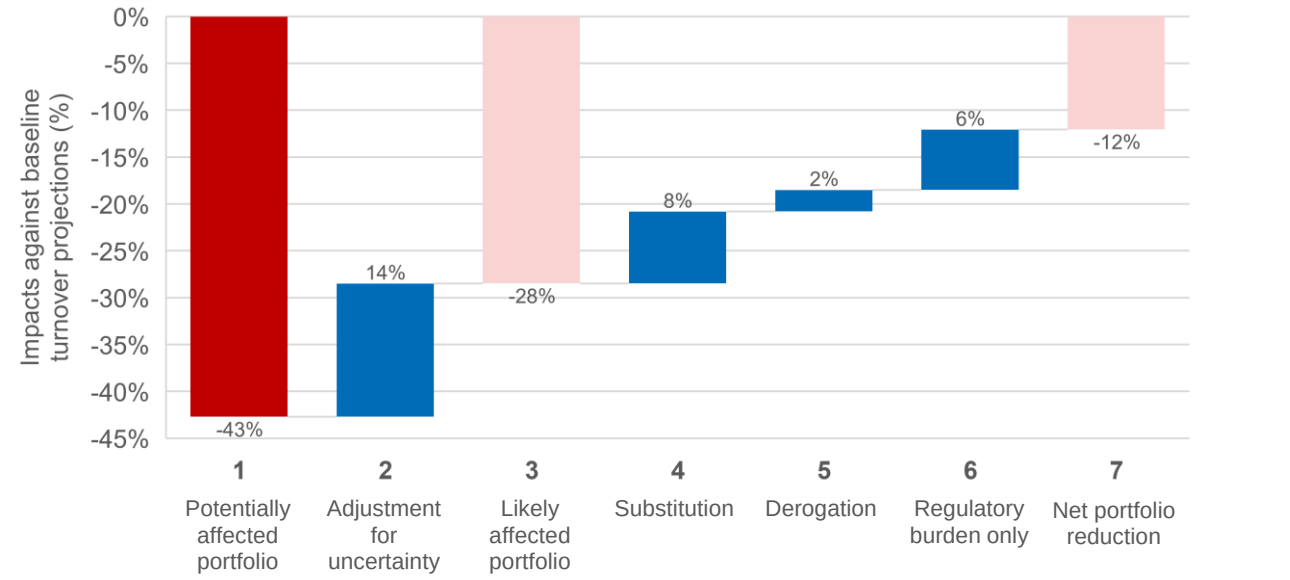
The rest of the products that would only be affected by changes to CLP will be subject to increased regulatory burden. Business will adjust capital and/or R&D expenditure plans and manufacturing or operating processes more broadly to adhere to new legislative requirements or mitigate any adverse effects.

In this case, the evidence collected also suggests that businesses would have some capacity to pass some of this regulatory burden through to their clients. Additionally, the survey responses suggest that overall sales of the EU chemicals sector are not very responsive to price changes. Therefore, the increase in regulatory burden is unlikely to affect the market significantly, albeit this is uncertain. For example, customer preferences may change and strong and/or growing competition from players based outside of the EU may affect this capacity of firms to pass costs through to their customers with limited market impact. For companies that are subject to multiple changes as a result of the CSS, the regulatory burden may be expected to increase due to cumulative effect.

Finally, Figure 4-2 below illustrates the different steps of the impact pathway statically, from the estimation of the total potentially affected portfolio to the turnover losses that are expected to result from the introduction of the policy changes considered in this study (central estimates).

[53] ECHA (2021) Transparent progress in addressing substances of concern – Integrated Regulatory Strategy Annual Report 2021. Available from: https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2020_en.pdf/646c8559-360d-f6ab-bfb7-02120eab52fa

Figure 4-2 Static stepwise representation of the portfolio in scope of being affected by the policy changes and expected responses from businesses (in percent of baseline turnover)



Source: Ricardo analysis based on Eurostat data and a bespoke survey to chemical companies.

In brief, the total potentially affected product portfolio from potential changes to the GRA and CLP (**Step 1**) can be adjusted by a weighting for F1/F2 classifications (**Step 2**) that leads to estimates of the most likely affected portfolio, which is equivalent to 28% of the baseline turnover or market (**Step 3**).

Around 8 percentage points of this market will likely be substituted/reformulated (**Step 4**), and 2 percentage points will not be discontinued thanks to derogations (**Step 5**). In addition, around 6 percentage points of the market will not face pressures for market withdrawal and will only be affected by increased regulatory burden (**Step 6**).

Therefore, this means that changes to CLP and GRA, when accounting for potential business responses, could lead to a reduction in product portfolio/business (in turnover terms) of around 12% or equivalent to €70 billion of the 2019 market (**Step 7**).

4.3.3 Costs and benefits driven by the impact on the EU chemicals sector

To further assess the net impacts of these policy options on the EU chemicals sector, a baseline and three policy scenarios were developed:

- The sectoral **baseline** (2019-2040) was developed by employing statistical techniques and trend analysis on publicly available evidence of the turnover from Eurostat's Structural Business Statistics[54]. This baseline scenario assumes that CSS is not implemented, GRA is not extended, and CLP remains unchanged.
- Policy **Scenario 1** considers the addition of hazard classes to CLP and extension of the GRA over a gradual implementation timetable, as outlined in Table (and Figure 4-1). In this scenario, new hazard classes are introduced within the CLP framework. As substances are (re)classified according to CLP over time, they would also be affected by GRA restrictions/bans. These products would be withdrawn from the market unless they are substituted, reformulated and/or derogations are secured. In addition, a quarter of products that are only affected by CLP (that is, not covered by the GRA extension) would also face pressures to withdraw from the market or substitute/reformulate. In a context where both CLP and GRA changes are implemented simultaneously, this impact from CLP only is estimated to be relatively small.
- **Scenario 2** assumes a faster, 5-year implementation timetable of the expected changes to the GRA and CLP. This includes the entry into force of all new hazard classes and all the extensions to the

[54] Ibid footnote 23

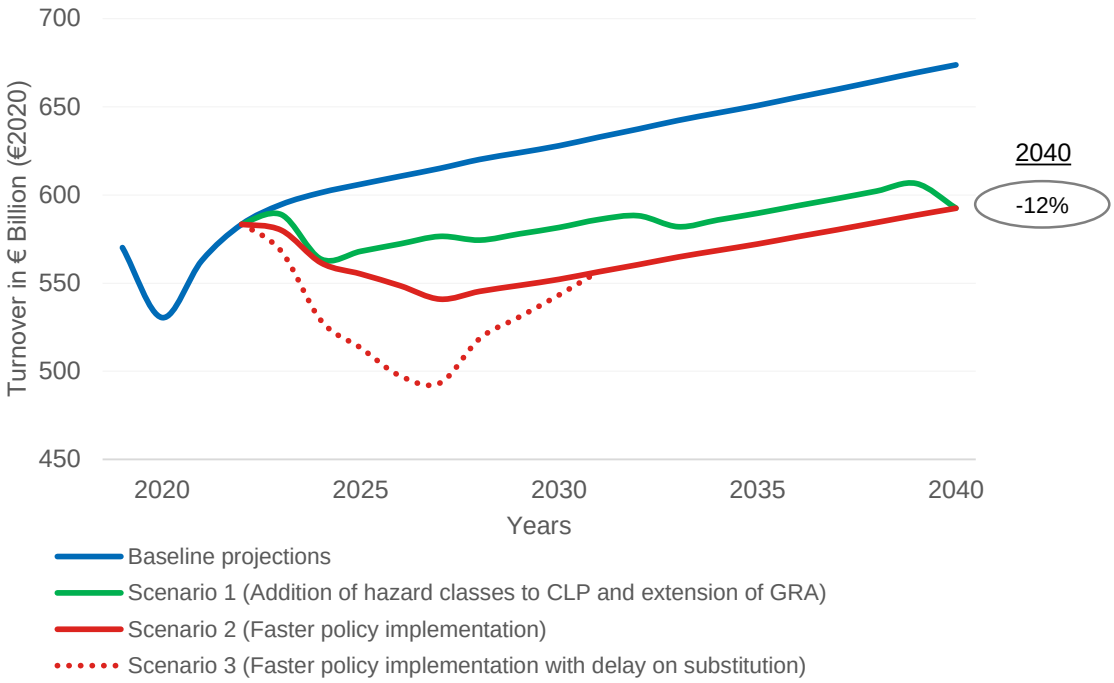
GRA. The faster implementation would require earlier and faster withdrawal of substances/ products from the market or their substitution and reformulation. Over time, however, the size of the EU chemicals market is estimated to converge to Scenario 1 levels.

- **Scenario 3** considers that, especially if the policy changes are implemented quickly such as in Scenario 2, businesses may need time to adapt so they can bring substitutes and/or reformulated products to the market. Based on the available evidence[55], it has been assumed that companies may need, on average, around 5 years to adjust their operations and place their substitutes and/or reformulated products on the market. This would lead to larger turnover losses earlier on. Over time, sectoral turnover would also converge to the levels estimated in earlier scenarios.

The net impacts on the EU-27 chemicals sector and the knock-on effects on the EU-27 economy in each of these policy scenarios were analysed against the baseline. By 2040, all policy changes have been implemented and taken effect in all three scenarios.

This analysis reveals that **EU chemical companies would lose between €47 billion to €81 billion of turnover per year on average between 2023 and 2040, when compared to baseline projections.** The extent of this reduction will depend upon the scope and timetable of the legislative changes as well as the type of businesses responses expected, illustrated by scenarios in Figure 4-3. In 2040, in any of the policy scenarios considered in this study, sectoral turnover is estimated to be around €80 billion lower than in the baseline.

Figure 4-3 Estimated impacts on the turnover of the EU chemicals sector against the baseline scenario (€ 2020)



Source: Ricardo analysis based on Eurostat data and a bespoke survey to chemical companies.
Note: The Y-axis has been truncated for ease of observation of differences between impact scenarios.

The direct contribution of the sector to GVA would be between €13 and €23 billion lower per year over the period 2023-2040, on average, when compared to the baseline. When adding indirect and induced effects, **the total contribution of the EU chemicals sector to GVA would be between €40 and €68 billion lower per year over this period, on average. This would be the equivalent of shaving between 0.3 and 0.5 percentage points off the EU-27 GDP and would affect Member States differently, depending on the contribution of their chemicals sector to their overall economy.**

[55] ECHA (2020) *"Impacts of REACH restriction and authorisation on substitution in the EU"*; DOI: 10.2823/39789. and ECHA (2021) *"Costs and benefits of REACH restrictions proposed between 2016-2020"*. DOI: 10.2823/122943

It is also estimated that operating, capital and R&D expenditures would decline when compared to the baseline. These net reductions, however, would be driven by the significant losses that are estimated for the size or operations of the EU chemicals market. These estimates do not suggest that there will be any cost savings from the adoption of the legislative changes. In fact, unit expenditure is estimated to increase. For example, the 'ratio of CAPEX to turnover' is likely to increase against the baseline by between 2%-5% on average over the period 2023-2040, driven primarily by additional investment requirements for substitution and/or reformulation. Similarly, the 'ratio of OPEX to turnover' is estimated to increase against the baseline by between 1.5%-3% on average over the same period, due to increased regulatory requirements and, where relevant, higher operating expenditure from manufacturing substitutes and/or reformulated products.

The changes to GRA and CLP would also affect the sector's employment. It is estimated that, by 2040, over 40,000 jobs in the EU chemicals sector would be lost against the baseline scenario, which is equivalent to 3% of the baseline chemicals workforce. **These impacts would have knock-on effects in the EU economy, which could lead to losing over 124,000 jobs by 2040 when compared against the baseline. This is equivalent to shaving around 0.1 percentage points off total employment in the EU-27.**

The Table below summarises some of these impacts on key business and economic indicators against the baseline and across three scenarios.

Table 4-3 Annualised impacts on selected business and economic indicators of the EU chemicals sector, against the baseline scenario (%)

Themes (business or economic indicators)	Scenario 1 (Addition of hazard classes to CLP and extension of the GRA)	Scenario 2 (Faster, 5-year implementation timetable)	Scenario 3 (Faster implementation timetable with substitution/ reformulation difficulties)
Turnover (first order effects)	A loss of €47 billion per year on average against the baseline	A loss of €67 billion per year on average against the baseline	A loss of €81 billion per year on average against the baseline
Total GVA contribution (*direct, indirect, induced*)	A loss of €40 billion per year on average against the baseline	A loss of €57 billion per year on average against the baseline	A loss of €68 billion per year on average against the baseline
Regulatory burden	An additional annualised burden of €434 million each year over the period	An additional annualised burden of €518 million each year over the period	An additional annualised burden of €518 million each year **with a delay**
Total employment contribution (*direct, indirect, induced*)	77,000 fewer jobs, on average, when compared to the baseline in any given year	106,000 fewer jobs, on average, when compared to the baseline in any given year	126,000 fewer jobs, on average, when compared to the baseline in any given year

Over half of the chemical companies surveyed expect that the policy proposals will affect their competitiveness negatively or very negatively; less than 40% of respondents did not expect any significant impacts on their competitiveness; and around 5% reported expecting a positive impact.

Chemical companies (77%) also expect that their exports from the EU-27 would be reduced when compared to the baseline, as a result of the changes to GRA and CLP. This would exacerbate the trends observed in the last decade, that is, the EU chemicals sector is likely to continue to lose global market share.

Moreover, while the EU chemicals industry experiences the restrictions imposed by the extension of the GRA and the changes to CLP, the majority (86%) of chemical companies participating in a survey for this study expect an increase in illicit imports of professional and consumer products into the EU-27 as a result of the decrease in product availability from the adoption of these policies.

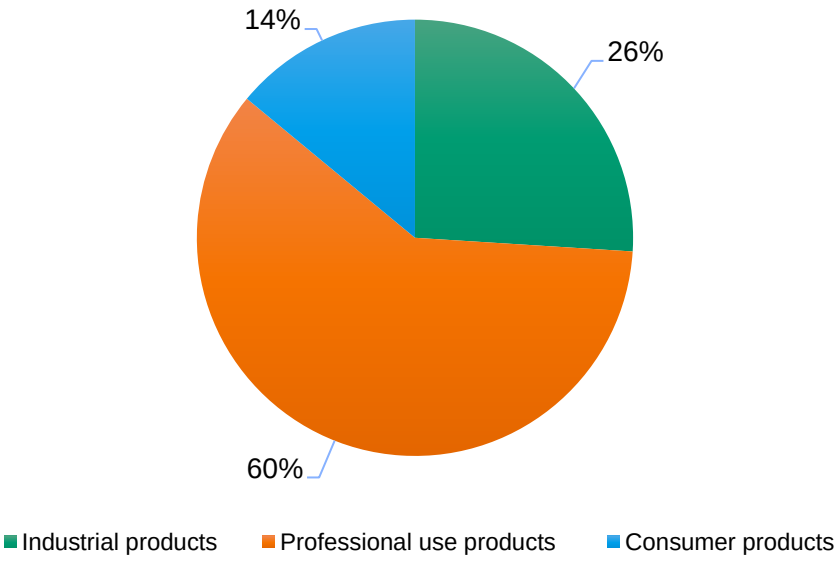
Illicit trade of restricted substances, mixtures and/or articles is a major concern among European chemicals companies, which is underpinned by the expectation that any reduction in the EU's supply of chemicals products induced by policy changes would become a market opportunity for producers from outside of the EU.

There is also the need to consider the impact of these restrictions on consumers. By targeting such a large number of products, consumer choice is reduced. Although there is likely to be benefits to society from the increased protection of human health and the environment as a result of these policy changes, the lack of consumer choice in a digital age may also lead to more consumers purchasing products online from outside the EU, increasing the illicit trade in non-compliant products.

The results of this assessment highlight that changes to CLP and the GRA, especially the latter, may lead to the reduction in manufacturing and/or use of chemical products currently on the market.

The **impact on downstream users** warrants **further exploration**. The analysis has shown that **60% of products in scope** to be impacted by the addition of hazards to CLP and the extension of the GRA are **professional products** (74% professional and consumer products) **(**see Figure 4-4**)**.

Figure 4-4 Potentially Affected Products by User Group



The impacts on these products have been estimated and the results suggest that the **downstream user sectors** that could be **most significantly impacted** are:

- **Polymer preparations and compounds, paper and board products, inks and toners,** all of which may be used for **food contact materials;**
- **Paints and coatings;**
- **Washing and cleaning products;**
- **Adhesives and sealants;**
- **Cosmetics and personal care products;**
- **Lubricants and greases;**
- **Biocidal products and plant protection products.**

As a result, it could prove difficult for the EU to achieve the aim stated in the CSS to "*strengthen its open strategic autonomy with resilient value chains and diversify sustainable sourcing for those chemicals that have essential uses for our health and for achieving a climate-neutral and circular economy*"[56].

To mitigate this, support would need to be provided to the chemicals industry through a clear implementation roadmap and the use of additional mechanisms be that financial, regulatory or additional time to respond to any policy changes, which could facilitate innovation and allow for new, more sustainable products to be brought to the market.

[56] Ibid footnote 12

Further analysis would be needed to assess whether the estimated costs to the EU-27 chemicals sector and the wider economy could be outweighed by any impacts of the proposed policy options on health, the environment and other economic impacts not considered in this study.

4.4 BAN ON EXPORTS SUBJECT TO THE GENERIC RISK APPROACH, REACH RESTRICTION OR AUTHORISATION

This sub-section seeks to determine the business impacts of a ban on exports subject to the generic approach to risk management, REACH restriction or authorisation for EU[57] companies and related sectors.

4.4.1 Policy Options Considered

The CSS states that the EU will "*lead by example, and, in line with international commitments, ensure that hazardous chemicals banned in the European Union are not produced for export, including by amending relevant legislation if and as needed*"[58].

Presently, certain banned or severely restricted chemicals (e.g., SVHCs), and the products that contain them, can still be manufactured within the EU for export to non-EU countries subject to additional measures. This trade in products that are banned in the EU has been heavily criticised. Regulation (EU) No 649/2012[59], also known as the Prior Informed Consent (PIC) Regulation permits the export of banned or severely restricted chemicals through placing an obligation on companies to appropriately inform any importers of relevant risks and of any existing restriction and bans.

The Terms of Reference for the Impact Assessment for potential amendments to REACH, included consideration of a potential horizontal sub-option to facilitate the prevention of banned chemicals being manufactured and exported.[60] This possibly indicates an intention to implement or at least review the CSS action of prohibiting the export of banned chemicals through REACH, by means of clarification or changes. At the time of writing (June 2022), the Commission Impact Assessment has not been published and so the final option selected for regulation of exports is still uncertain, although indications suggest that the export ban may instead be implemented under the PIC Regulation. It has been assumed that the economic impacts of an export ban would be the same, regardless of whether it is implemented under REACH or the PIC Regulation, although it is acknowledged that the remit of these pieces of legislation is not identical, with the PIC Regulation implementing international conventions such as the Rotterdam Convention. Concern has been raised regarding the risk to third countries that may require these banned products for essential applications e.g., medical devices, raising questions as to whether the EU should impose the regulatory requirements of the EU on third countries by preventing access to products that were previously manufactured in the EU for export.[61]

The CSS actions could result in the banning of products for export to non-EU countries that are subject to the GRA, REACH restriction or authorisation in the EU, as well as restrictions in any other relevant sector-specific legislation. Once substances have been through the process of harmonised classification, substances, mixtures and possibly articles containing the CLP-classified substances that are subject to restrictions or bans in the EU would be affected by generic restrictions on their export.

Based on this, the following list of products have been identified as relevant for the assessment of business impacts of an EU export ban:

- Products subject to current REACH restriction
- Products subject to current REACH authorisation
- Products subject to current GRA under REACH and sectoral legislation (BPR, PPPR, Cosmetic Products Regulation, Toy Safety Directive)

[57] While the UK was one of the largest exporters of banned chemicals when part of the EU, the proposed export ban will not apply to the UK and as such the UK is treated as a third country in this context.

[58] Ibid footnote 12

[59] Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32012R0649

[60] European Commission (2021) Terms of Reference for 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. Available at: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/3be62c67-7955-4e50-afe6-0afc2a74ed53/details

[61] European Commission (2021) Stakeholder Workshop Report for 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. Available at: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/b8e8435f-0d84-49b9-aed6-8624db2dfaf4/details

- Products that may be subject to GRA in the future (professional and consumer uses - C and F1 classifications only for specific target organ toxicity repeat dose and single dose (STOT RE and SE) cat 1 and 2, respiratory sensitiser cat 1, 1A, 1B, immunotoxic, neurotoxic)
- Products that may be subject to GRA in the future (professional and consumer uses - C and F1 classifications only for substances of very high concern (SVHC) classifications (carcinogen mutagen, reprotoxin (CMR) cat. 1A and 1B; ED; persistent, bioaccumulative, toxic (PBT); very persistent, very bioaccumulative (vPvB); persistent, mobile, toxic (PMT); very persistent, very mobile (vPvM)).

To note, due to uncertainties, the restriction roadmap has not been included in these assumptions. In reality, the export ban is likely to include three stages of restrictions: existing restrictions, those under development (restriction roadmap), future GRA/ SRA restrictions. In this respect, the export ban does not only extend the impact of GRA, it also extend the scope of restrictions already in force. The hazard classes considered for the assessment of the export ban have also been reduced compared with the GRA assessment, and therefore do not include CMR cat. 2, skin sensitisers or aquatic chronic cat. 1 substances.

The policy assumptions assessed in this Study are outlined in Table 4-1. The dates for assumed entry into force have been carried forward from the Phase 1 study for GRA in order to maintain consistency but it is acknowledged that these timeframes may change with ongoing Commission discussions.

These, and other assumptions, offer a workable and reasonable approach to assessing impacts of the policy options considered, albeit with limitations.

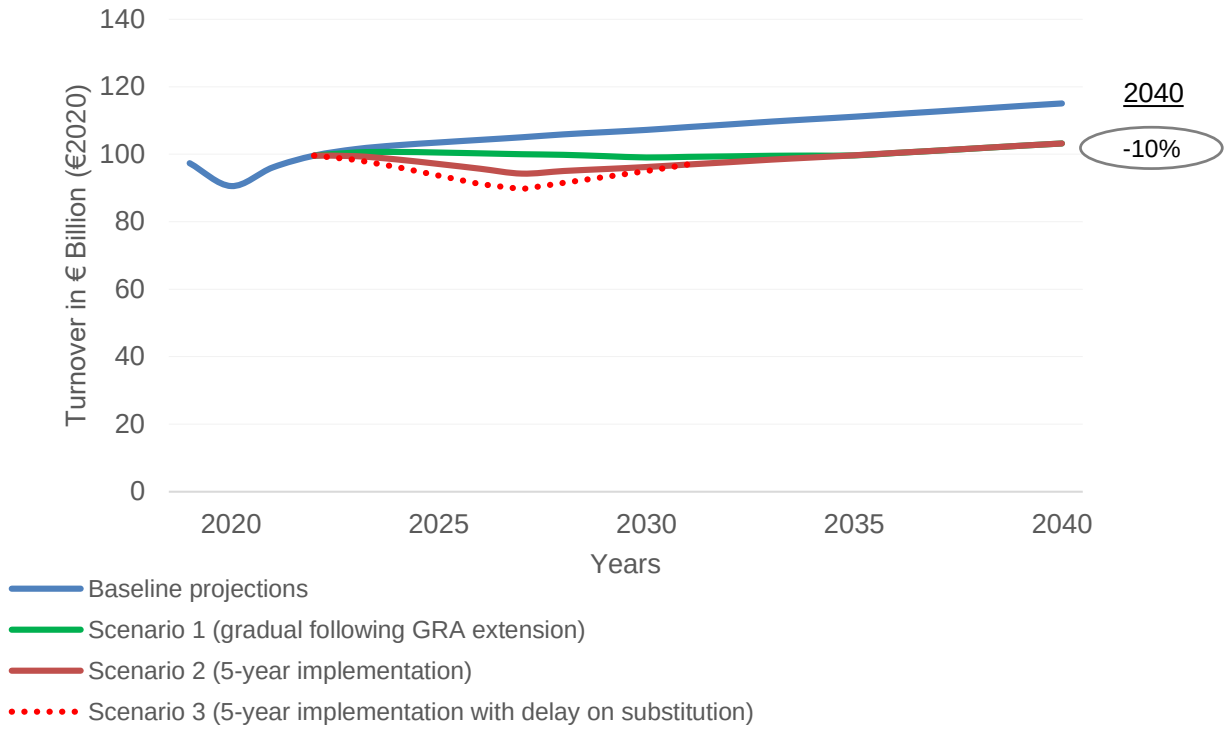
4.4.2 Business impacts of a ban on exports subject to the generic approach to risk management, REACH restriction or authorisation

47 chemical companies with an export portfolio were asked to consider the products in their 2019 product portfolio that could be affected, if the export ban were to be fully adopted with immediate effect (i.e., in 2023). 35 of those companies had also participated in the consultation for the module on impacts of the CLP and GRA. To note, it is accepted that REACH revision is now estimated to enter into force in 2025, but to be consistent with the CLP and GRA assessments of this study, 2023 has been used as the first year of change. A baseline and three policy scenarios were developed to specifically estimate the net impacts of the introduction of an export ban on the EU chemicals sector. The three scenarios were developed based on the scenarios outlined in Section 4.3.3. The sectoral **baseline** (2019-2040) was developed by employing statistical techniques and trend analysis on publicly available evidence of the turnover from Eurostat's Trade Statistics[62] and Structural Business Statistics[63]. This baseline scenario assumes that the proposed restriction on exports is not implemented. At the time of the survey, exports constitute 18% of the EU-27 chemical output (i.e., in 2019 as per the latest official statistic). However, this proportion has recently changed: for the first time, the EU is a net importer in the last quarter. This new development was not considered in this assessment as it developed after the analysis was completed.

This analysis reveals that **EU chemical companies would experience annualised losses in turnover from exports that would range from €7 billion to €11 billion per year between 2023 and 2040, when compared to baseline projections.** The extent of this reduction depends upon the scope and timetable of the legislative changes as well as the type of businesses responses expected, illustrated by scenarios in Figure 4-5. In 2040, sectoral turnover is estimated to be around €11.8 billion lower than in the baseline in all policy scenarios, albeit this is inherently uncertain and will depend on factors such as demand patterns, technological development, innovation and international competitiveness. **There would be cumulative losses for companies which place products on the EU within scope of the GRA extension and on the export markets within scope of the export ban.**

[62] Eurostat (2022) *Trade by NACE Rev. 2 activity sector*. [online] Eurostat Available from: Database – Trade by NACE Rev.2 activity sector - Eurostat (europa.eu) [Accessed 03/2022].
[63] Ibid footnote 21

Figure 4-5 Estimated impacts of the export ban on turnover from exports of the EU chemicals sector against the baseline scenario (€ 2020)



The direct contribution of the sector to GVA would be between €2.2 billion and €3.2 billion lower per year over the period 2023-2040, on average, when compared to the baseline. When adding indirect and induced effects, **the total contribution of the EU chemicals sector to GVA would be between €6.5 billion and €9.5 billion lower per year over this period, on average.**

Similarly to the GRA part, it is also estimated that operating, capital and R&D expenditures would increase when compared to the baseline. These net increases would be driven by the capital and R&D investments required to achieve the intended substitution of restricted chemicals. As a result, unit expenditure is estimated to increase. For example, the 'ratio of CAPEX to turnover' is likely to increase against the baseline by around 7.1-8.6% on average over the period 2023-2040, driven primarily by adjustments to the manufacturing processes and completing the required investments for effective substitution and reformulation. Similarly, the 'ratio of OPEX to turnover' is estimated to increase against the baseline by around 5% on average over the same period, due to increased regulatory requirements and, where relevant, higher operating expenditure from manufacturing substitutes and/or reformulated products.

The introduction of the export ban would also affect the sector's employment. It is estimated that, by 2040, around 6,100 jobs in the EU chemicals sector would be lost against the baseline, which is equivalent to 0.5% of the baseline workforce of the whole chemicals sector. **These impacts would have knock-on effects in the EU economy, which could lead to losing a total of 18,600 jobs by 2040 when compared against the baseline (average annual 12,700, 15,700 and 17,700 fewer jobs in Scenarios 1, 2 and 3, respectively, between 2023 and 2040). This is equivalent to shaving around 0.01 percentage points off total employment in the EU-27.**

Table 4-5 below summarises some of these impacts on key business and economic indicators against the baseline and across three scenarios.

Table 4-4 Annualised impacts on selected business and economic indicators of the EU chemicals sector, against the baseline scenario (%)

Themes (business or economic indicators)	Scenario 1 (Gradual implementation timetable)	Scenario 2 (Faster, 5-year implementation timetable)	Scenario 3 (Faster implementation timetable with substitution/ reformulation difficulties)
Turnover (first order effects)	A loss of €7.3 billion per year on average against the baseline	A loss of €9.5 billion per year on average against the baseline	A loss of €11.0 billion per year on average against the baseline
Total GVA contribution (*direct, indirect, induced*)	A loss of €6.5 billion per year on average against the baseline	A loss of €8.3 billion per year on average against the baseline	A loss of €9.5 billion per year on average against the baseline
Regulatory burden	An additional annualised burden of €440 million each year over the period	An additional annualised burden of €530 million each year over the period	An additional annualised burden of €560 million each year with a delay
Total employment contribution (*direct, indirect, induced*)	12,700 fewer jobs, on average, when compared to the baseline in any given year	15,700 fewer jobs, on average, when compared to the baseline in any given year	17,700 fewer jobs, on average, when compared to the baseline in any given year

More than 60% of the chemical companies surveyed expect that the introduction of the export ban would affect their competitiveness negatively or very negatively; less than 36% of respondents did not expect any significant impacts on their competitiveness; and no company reported expecting a positive impact. These impacts are not likely to be captured in full in the estimates summarised in Table 4-5.

Moreover, the majority (77%) of chemical companies surveyed for this study expect that manufacturers from outside of the EU-27 would increase their production to close any gaps in supply caused by a reduction in exports from the EU due to the proposed export ban. At the same time, almost a third of the surveyed companies plans to carry out or has already shifted (13%) its production elsewhere, outside of the EU-27.

The results of this assessment highlight that introducing a ban on exports subject to GRA and on other restrictions and authorisations already in place may lead to the reduction in manufacturing and export of chemical products from the EU-27. This impact comes in addition to the GRA impact.

5. INTRODUCTION OF A MIXTURE ASSESSMENT FACTOR UNDER REACH REGISTRATION

This section presents a case study analysis based on two substances that seeks to determine the business impacts of the introduction of a Mixture Assessment Factor under REACH registration. It is presented as follows:

- Section 5.1 – Context and baseline
- Section 5.2 – Case study methodology
- Section 5.3 – Business impacts of the introduction of a Mixture Assessment Factor under REACH registration.

5.1 CONTEXT AND BASELINE

5.1.1 Policy Context

Currently, the risk of chemicals in the EU is usually assessed for individual substances, or sometimes intentional mixtures for particular uses. In reality, the environment, workers and consumers are exposed to unintentional mixtures of chemicals, the risk of which is difficult to characterise. To address this the Commission shall "*assess how to best introduce in REACH (a) mixture assessment factor(s) for the chemical safety assessment of substances*". As it is not possible to identify and regulate every single possible combination of chemicals that humans and the environment may be exposed to from different sources over time, the introduction of a MAF aims to account for some of the uncertainty of mixture effects in risk assessment.

The risk of single substances to humans and the environment can be assessed using risk characterisation ratios (RCRs). RCRs are ratios between (predicted) exposure levels and no-effect concentrations. The RCRs for all possible exposures (i.e. for all relevant routes of human health exposure, human populations, environmental compartments, durations) associated with each exposure scenario are used to quantitatively, or semi-quantitively, assess whether the risk of the substance is controlled and the substance is "safe" to use. When the RCR value is less than 1, it is assumed that the level of substance exposure poses no significant risk, when this value is greater than or equal to 1, it is assumed that exposure concentrations are higher than the threshold for effects, and as such the risk is deemed "unacceptable" and measures must be taken to reduce this value.

The MAF multiplies the RCR by a generic factor, acting as a safety margin to cover any unintended cumulative or cocktail effects of mixtures. The MAF to be applied is yet to be defined and remains under assessment, but values ranging from 1-10, up to 100, have been suggested by academia and authorities in the past[64,65,66]. For this exercise, a MAF of 10 has been applied to the current RCRs of selected chemical substances as a realistic scenario, resulting in all RCRs of greater than or equal to 0.1 demonstrating an unacceptable risk once the MAF has been introduced. The work forms the basis of a consultation with chemical companies to ascertain the business impacts that the introduction of a MAF would have.

Given the complexity of the application of MAF and the scope of this Study, a case study approach was selected to illustrate how a range of businesses, that is, REACH registrants, could be affected. The potential knock-on implications on the chemicals industry associated with the selected registrations and the broader economy were also characterised to the extent possible, more qualitatively.

Due to the consultation being limited to registrants of the substances (substance manufacturers or importers), supply chain effects have not been quantified in detail and may present a larger economic impact than is provided in this report.

[64] RIVM (2016) Addressing combined effects of chemicals in environmental safety assessment under REACH – a thought starter

[65] Sarigiannis. D. & Hansen. U. (2012) Considering the cumulative risk of mixtures of chemicals – A challenge for policy makers. Environmental Health. 11. 18

[66] Tørsløv. J., Slothus. T., Christiansen. S. (2011) Endocrine disruptors: combination effects. Nordic Council of Ministers

5.2 CASE STUDY METHODOLOGY

Four substances were selected based on their volume, multiple uses and the responses that would be needed as a result of the MAF e.g. low business impact – revision of existing assessment, high business impact – reduction in volume placed on the market/ withdrawal. Following this selection, the methodology comprises the following six steps:

- **Step 1: Technical review of Chemical Safety Reports** (CSRs). The four selected substances cover low, medium, and high potential human health and environmental impacts, thus representing the breadth of potential impacts on the EU chemicals industry. The implications of applying a MAF of 10 to the RCRs of each CSR were investigated. For RCRs ending at values higher than 1, experts employed a framework developed by ECHA[67] to consider the actions that the registrants may need to take in order to bring RCRs below 1 when a MAF of 10 was applied (i.e., below 0.1 before the MAF is introduced). The output of this step was a list of possible actions that registrants may wish to take to bring the RCRs below 1 and thus continue supporting as many of the current uses as possible.
    - **Actions that may be required[68]:**
        - Adjust values for Risk Characterisation Ratios without substantially changing the exposure assessment;
        - Revise some or all exposure scenarios based on existing data through refining/changing the assessment method or single input parameters;
        - Generate data (environmental testing, human health testing and/or exposure measurements) in order to review (lower) assessment factors or level of conservatism in exposure estimates;
        - Additional risk management measures to be implemented at professional/consumer user level;
        - Limit the use of the substance, with or without possible substitution (e.g., industrial user only, upper concentration limit on products, no use in water contact, etc.).
- **Step 2: Map and screen the business and economic impact categories.** A longlist of economic impacts was developed and screened, following the methodology in Section 2. From these, two business and economic impact categories were identified as likely to be significant for a more in-depth assessment. Across these impact categories, different types of economic costs and benefits were considered, and a few indicators were selected to assess impacts quantitatively (See Table).

Table 5-1 Sectoral indicators selected for baseline characterisation

Categories	Indicators
Conduct of business (and economic contribution)	• Business turnover (€ millions) • Gross Value Added (€ millions), approximately capturing the sector's contribution to Gross Domestic Product • Capital expenditure or investment (€ millions) • Operating expenditure (€ millions)
Employment	• Number of jobs supported (Number of FTEs)

- **Step 3: Stakeholder consultation and evidence gathering.** Registrants of the four selected substances were engaged as part of this project. This was a central task that provided the evidence required to progress with the development of the case studies of potential impact of the application of a MAF of 10. The consultation activities and data analysis carried out in this Case Study followed the methodology in Section 2. These activities included a targeted consultation via online survey, targeting members of the REACH registration Consortia for each of the selected substances. Interviews with a

[67] ECHA (2020) Mixture Assessment Factor (MAF): Impact on registrant's CSR? Analytical approach and initial observations. Presentation
[68] Ibid footnote 67

range of the survey respondents were also carried out to test and challenge their responses and ensure they would be interpreted effectively. The consultation activities were complemented by a rapid literature review. Sufficient responses to the consultation were received from two Consortia only, meaning that only two substances could be3 carried forward for assessment of impacts.

- **Step 4: Define and characterise the baseline scenario against which to assess the MAF.** The study considered how the EU-27 market of the selected substances would likely evolve without any further policy changes in the EU chemicals legislation. This work was inspired by the Better Regulation Guidelines[69], and particularly drawing from Tool #60 (Baselines). This step could only be taken for the two substances for which sufficient data was obtained.
- **Step 5: Assess the business and economic impacts of the policy options.** Business and economic impacts were assessed for two substances for which sufficient evidence was collected as part of the stakeholder consultation activities (one representing potentially higher impact on human health and one lower impact on human health and the environment). The quantitative analysis was based on the Better Regulation Toolbox[70], e.g., Tool #57 (Methods to assess costs and benefits). The economic and statistical methods employed for the quantification of policy effects were selected based on the suitability for analysis of the evidence collected through a business survey and interviews.
- **Step 6: Conclusions**. The quantitative and qualitative evidence on business and economic impacts for the two cases was employed to present the implications of a MAF of 10. These implications have also provided a basis to develop insights and/or conclusions for consideration by policymakers as they continue to develop the options and ambitions set out within the CSS.

A list of key assumptions developed for the analysis of business impacts from the introduction of a MAF under REACH are summarised in the table below.

Table 5-2 Shortlist of policy options and assumptions used in the analysis for the addition of a MAF to REACH

Action	Concrete Policy Option Outlined in CSS	Assumed regulatory action	Assumed entry into force
MAF	Introduction in REACH of a Mixture Assessment Factor (MAF) for the chemical safety assessment of substances	Introduction of a MAF of 10	2025

5.3 BUSINESS IMPACTS OF THE INTRODUCTION OF A MIXTURE ASSESSMENT FACTOR UNDER REACH REGISTRATION

5.3.1 Baseline

Businesses registering four selected substances with broad uses were consulted and a sample of four or more respondents were secured for two of these substances. For the two other substances, the response rate did not allow to process the information in line with rules on competition law.

Table 5-3 Baseline

	Volume placed on the market (tonnes/ year (2019))	Turnover (€/year (2019))	EU-27 GVA (€/year (2019))
Substance 2	0.2-12 million tonnes	€140-320 million	c. €60 million

[69] Ibid footnote 16
[70] Ibid footnote 16

	Volume placed on the market (tonnes/ year (2019))	Turnover (€/year (2019))	EU-27 GVA (€/year (2019))
Substance 4	1-3 million tonnes	€2,300-4,500 million	c. €900 million

Without any further policy intervention, the substance registrants estimate that their turnover could grow between 2%-4% per year, on average, over the next 20 years. These businesses employ a total of 4,700 to 10,500 people (full-time equivalent), which would be estimated to grow, on average, between 1%-2% per year, over the timeline. These businesses also make capital investments of hundreds of millions of euros and purchase goods and services worth billions of euros each year from other businesses in the EU-27 and internationally. As such, they also have a significant economic footprint.

5.3.2 Business Impacts

Table provides an overview of the actions that registrants identified for the two substances taken forward for the assessment of impacts.

Table 5-4 Impact scenarios and uncertainties

Case studies	Main business impact scenario	Key uncertainties
Substance 2	The registrants consulted would generally **continue manufacturing the substance in the EU-27, whilst also taking the following action:** • Updating risk assessments • Revising exposure scenario • Generating emission data • Introducing further risk management measures to reduce worker/professional exposure • Withdrawal of the substance (by up to 20% on average) as clients reduce their purchases of the product	The business responses and implications are **uncertain**. Therefore: • The lower bound impact would consider the best-case scenario from business responses. • As the majority of respondents would continue business activity in the EU-27, the upper bound impact assumes a worst-case scenario with some withdrawal of products and associated business activity.
Substance 4	The registrants consulted would generally **continue manufacturing and using the substance in the EU-27, whilst they would take significant action:** • Introduce further risk management measures to reduce worker/ professional exposure • Withdraw some products from the market (10% and likely significantly more) These registrants also estimate that their clients may reduce their purchases (by 10% or likely significantly more, on average).	The business responses and implications are **very uncertain**. Therefore: • The lower bound impact would include a scenario where registrants are able to support most uses of the substance by introducing risk management measures. Limited product withdrawal with no possible substitution or downstream response would be expected. • The upper bound impact includes some registrants shutting down their business activity in the EU-27 and moving some or all abroad and importing a more final product.

Based on these potential business responses, a rapid economic analysis was carried out to estimate the implications of a MAF of 10 on the chemicals industry and knock-on effects across the supply chain and wider economy. **This analysis revealed that the adoption of a MAF of 10 and the resulting business actions would have substantial impacts on their business activity and the associated supply chains due to the need to withdraw substances from the market and the introduction of stricter risk management measures which may reduce demand from customers further down the supply chain, due in part to the**

large investment needed. These impacts would be exacerbated by the additional regulatory burden that the registrants would face and would have direct implications on the EU-27's GDP, potentially resulting in direct losses of billions of euros in value added; and result in potential losses of thousands of jobs in the EU-27. These estimated impacts are outlined in Table below.

Table 5-5 Overview of business and knock-on direct economic impacts as a result of the introduction of a MAF of 10 in 2040, when compared to the baseline scenario

Case studies	Annual turnover loss (Million Euros)	Annual turnover loss (%)	Employment losses (FTE)	Employment losses (%)	Direct[71] GDP 'losses' (EUR)
Substance 2	23-77 million euros lost	8%-28% lost	50-150 jobs lost	5-18% lost	5-20 million euros lost
Substance 4	0.7-5.3 billion euros lost	10%-80% lost	500-5,600 jobs lost	5-53% lost	0.2-1.4 billion euros lost

The range of turnover losses from moderate to high indicate that impact is dependent on the responses required by businesses but also the number and type of uses of the substance. Further, these impacts may lead to a worsening of the competitiveness of the EU-27 industry and a shift towards increasing imports of final products, increasing the dependency on third countries for chemical substances and/or products previously manufactured and used in supply chains across the EU. **As a result, supply chains worth hundreds of billions would be affected and potentially disrupted, which would have additional negative economic implications across the EU.**

[71] This excludes any indirect and induced effects on the economy resulting from reductions in the manufacturing and use of these substances.

6. REACH REGISTRATION OF POLYMERS

This section seeks to determine the business impacts of the registration of polymers under REACH and is set out as follows:

- Section 6.1 – context and baseline
- Section 6.2– policy options considered
- Section 6.3 – business impacts of REACH registration of polymers

6.1 CONTEXT AND BASELINE

6.1.1 Policy Context

One of the key aspects of REACH[72] is 'no data, no market' (Article 5) meaning that substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered. REACH registration puts the responsibility on industry to collect information on the properties and uses of substances they place on the market above 1 tonne per year. Exemptions from registration exist, including polymers.

Despite gathering a broad knowledge base on the properties, risks and uses of chemicals in the EU, the CSS notes that a comprehensive knowledge base is still lacking for certain chemicals, hindering the proper management of products placed on the market. Polymers have become ubiquitous in daily life, but at present there is limited information available to authorities on the hazards, exposures, uses and subsequent risks of the polymers placed on the market in the EU, in part because they are not subject to REACH registration. As such, the CSS has committed to "*make a proposal to extend the duty of registration under REACH to certain polymers of concern*".

Article 138 of REACH places an obligation on the Commission to review certain aspects of the Regulation within defined timeframes. One of the reviews included the consideration of registration of polymers (Article 138(2)), as described in Box 6.

Box 6 Consideration of polymer registration (REACH Article 138(2))

"The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:

- *the risks posed by polymers in comparison with other substances;*
- *the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other."*[73]

The first of these reviews related to polymer registration was published in 2012[74], with follow up studies in 2015[75] and 2020[76]. In March 2020 the Commission put forward a proposal of a mandate for a CARACAL subgroup on polymers (CASG-Polymers). The purpose of the CASG-Polymers is to advise the Commission on how best to consider the outcomes of the 2020 study in its development of a proposal for registration of certain types of polymers. Since September 2020, the CASG-Polymers have discussed the intricacies of polymer registration at length, including grouping of polymers, definitions for polymer of low concern (PLC) and polymer requiring registration (PRR), and information requirements for PRRs.

[72] *Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).* The Official Journal of the European Union. Available from: https://echa.europa.eu/regulations/reach/legislation

[73] Ibid footnote 72

[74] RPA, Milieu, Gnosys (2012) Review of REACH with regard to the registration requirements on polymers

[75] BIO & PIEP (2015) Technical assistance related to the review of REACH with regard to the registration requirements on polymers

[76] Wood & PFA-Brussels (2020) Scientific and technical support for development of criteria to identify and group polymers for registration/ evaluation under REACH and their Impact Assessment

6.2 POLICY OPTIONS CONSIDERED

Whilst the CSS does not include detailed guidance on the proposed actions around polymer registration, it does indicate expected actions that will be taken by the Commission. These actions have been carried forward as policy options for this assessment. Assumptions have been developed by the study team and Cefic and are based on literature review of publicly available information. Downstream users who modify polymers were not accounted for in this survey, though it is acknowledged that some co-polymerisation is carried out by downstream users which may be within scope of polymer registration. Whether this activity is included in the polymer registration requirements would be dependent on the definition of polymer modification used by the Commission.

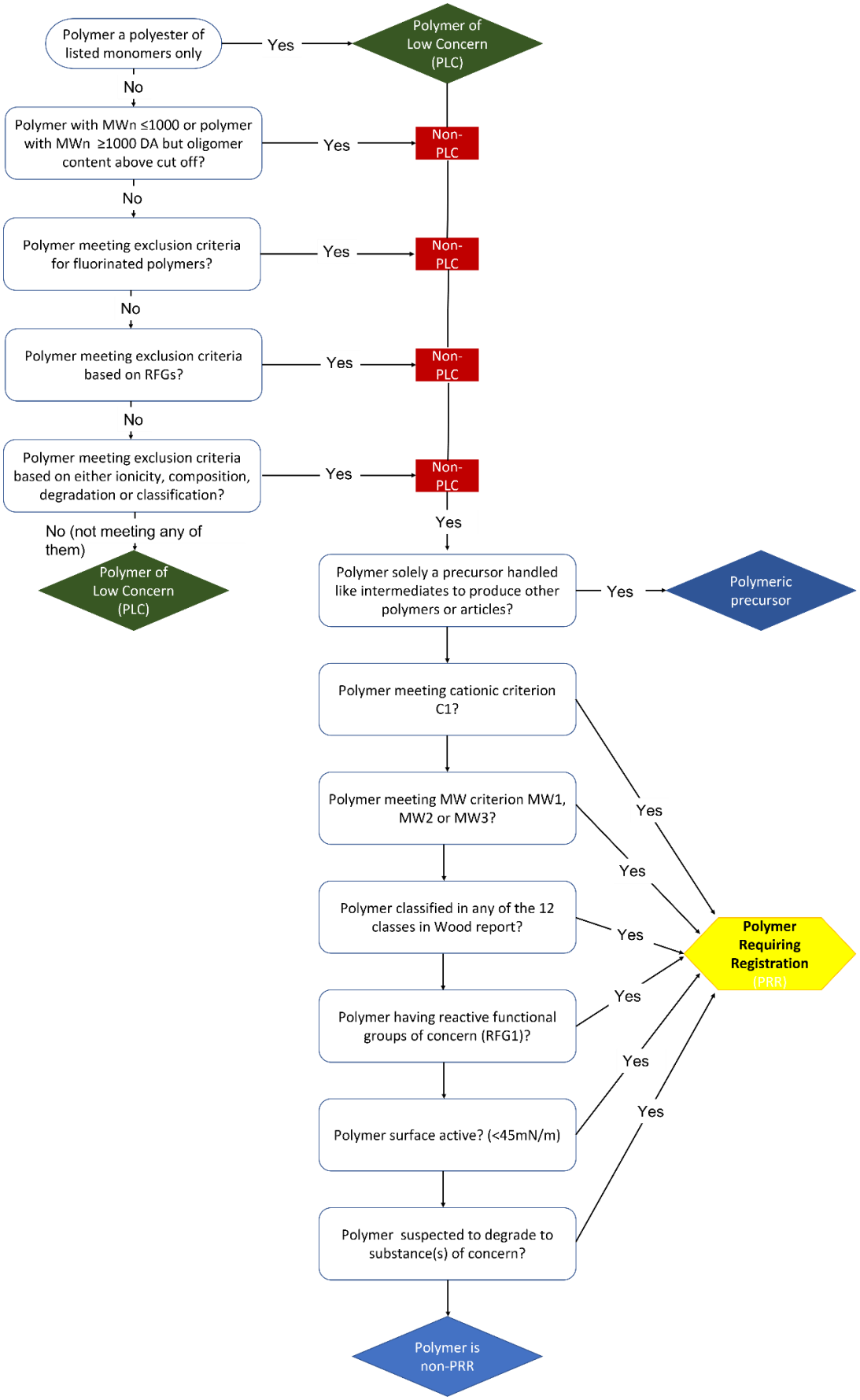
Polymer Registration

Polymer registration is a complex issue and remains the subject of continued discussion and refinement. This adds to the level of uncertainty when attempting to estimate the potential impacts of polymer registration on industry. As a starting point, the assessment uses the following criteria:

- All polymers (PLC, precursors, non-PRR and PRR) require notification to ECHA.
- Polymers of low concern do not need to be registered.
- Polymers requiring registration (PRR) need to register.
- Non-PRR and precursors do not need to be registered.

The PLC and PRR criteria used for this study are outlined in Figure 6-1.

Figure 6-1 PLC, PRR inclusion and exclusion criteria



Source: Adapted from European Commission (2021) PRR-Identification flowchart – Update 18 October 2021

Two policy options have been carried forward for assessment:

Policy Option 1 – REACH Standard Information Requirements (SIR)

The grouping strategy for a PRR group used for Policy option 1 is based on the polymers having the same CAS number or, in absence of CAS, based on the same reactants and within a 2% molecular weight.

The PLC and PRR criteria used in this assessment are those presented in the flow chart in October 2021. Information requirements are taken from the 2020 study and updated based on discussions in the CASG-Polymers up to January 2022.

These criteria and this approach have been adapted over time following discussions in the 7th and 8th meetings of the subgroup in February and May of 2022. The adaptations focused on the removal of the PLC-category and the use of a PRR/ non-PRR system. The reasoning for this approach was based on the expectation that most PLC would fall into the non-PRR category and therefore this could be simplified. The details on the information requirements for PRR were discussed further in these meetings and clearer indications were provided on the requirements for each type. Other key differences include the addition of certain tests e.g. OECD 118 and 119, introduction of assessment based on environmental degradability and hindered uptake; and extractability testing; and consideration of the number of "unfavourable" outcomes. **These adaptations occurred after the analysis for this study had begun and so could not be incorporated into the assessment.**

Policy Option 2 – ECETOC grouping and testing strategy

As the registration requirements for polymers are still the subject of discussion, this study considers a second Policy Option for the grouping of polymer for registration and the information requirements in order to identify whether there would be significant difference in economic impact.

ECETOC are a not-for-profit association whose work assesses existing research (or gaps therein) and suggests innovative and practical solutions that can be adopted towards policy change. ECETOC have a dedicated task force, established in 2018, that seeks to assess the human health and environmental safety of polymers.

Grouping of PRRs for the ECETOC testing strategy followed a simplified approach to the ECETOC grouping scheme in an effort to ensure that as many respondents as possible could participate.

The testing strategy has been selected from the tests featured in the Technical Report No. 133-2 and deemed to be appropriate or adaptable to polymers by ECETOC[77]. The second report in a three-part series on the Conceptual Framework for Polymer Risk Assessment (CF4Polymers) by ECETOC focuses on the applicability of analytical tools and it studies a large number of tests currently in use and under development[78]. Not all of the tests considered in this study have been included here as many were discussed as equivalents or alternatives. Instead the processes used here have been based on the proposed workflows in this ECETOC study focusing on physio-chemical properties, ecotoxicity, biodegradation and human toxicity. Workflows were provided on each area of interest by ECETOC and these were cross referenced with the third report in the study, a selection of case studies implementing the CF4Polymers framework[79]. From the tests selected as applicable, the proposed workflows and the modelled studies in Report no.133-3, a detailed testing strategy was produced.

Weightings were applied to each test within the testing strategies for Policy Options 1 and 2. Where tests are the same for both Policy Options, the same weightings have been used.

6.2.1 Assumptions

Table below summaries the assumptions that have been used in the analysis of business impacts.

[77] ECETOC, 2020, *Applicability of Analytical Tools, Test Methods and Models for Polymer Risk Assessment Technical Report No. 133-2*. Available from: TR 133-2 - The Applicability of Analytical Tools, Test Methods and Models for Polymer Risk Assessment - ECETOC

[78] Ibid footnote 77

[79] ECETOC, 2020, *Case Studies Putting the ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers) into Practice Technical Report No. 133-3*. Available from: ECETOC-TR-133-3-CF4Polymers-Case-Studies.pdf

Table 6-1 Overview of assumptions used for analysis of business impacts

Assumption	Timeline
Entry into force of registration requirements	2025
Transition period for completing registrations	2032

6.3 BUSINESS IMPACTS OF REACH REGISTRATION OF POLYMERS

First, a baseline and two policy scenarios were developed to assess the net impacts of this policy on the EU chemicals sector:

- The sectoral **baseline, i.e., no polymer registration,** (2019-2040) was developed by employing statistical techniques and trend analysis on publicly available evidence of the turnover from Eurostat's Trade Statistics[80] and Structural Business Statistics[81]. This baseline scenario assumes that the proposed registration requirements for polymers are not introduced.
- The two **policy options** (2019-2040) assume that registration requirements will **be introduced in 2025, with polymer manufacturers performing testing and submitting registration dossiers over a span of seven years**. Additionally, companies will have to update the registration of some PRR groups depending on changes to e.g., their tonnage band. It is assumed that this might happen twice for each company until 2040. The two policy scenarios differ in their **polymer grouping and testing strategies**. **Policy Option 1 applies REACH SIR, whereas Policy Option 2 applies ECETOC grouping and testing strategies.**

The options were analysed against the baseline, based on the evidence collected from 65 companies that participated in a bespoke survey. **To note, downstream users of polymers did not respond to the survey**. Table presents an estimation of the number of polymers that are placed on the market in EU-27 to understand the extent of the current polymer market. This is then broken down into the total number of polymers that meet the criteria for PLC and precursor as these polymers would not be subject to registration requirements. The polymers that would be subject to registration requirements are presented by Policy Option, with Policy Option 1 considering the number of Type 1, 2 and 3 PRR groups based on the CAS grouping strategy and REACH tonnage band for Policy Option 1; and based on the ECETOC grouping strategy for Policy Option 2. The PRR polymer group type is determined by the polymer number average molecular weight according to the following ranges: PRR Type 1: < 1 000 Da; PRR Type 2: 1000 – 10 000 Da; PRR Type 3: > 10 000 Da and the number of polymer groups within each type has been calculated from the evidence collected from the 65 survey participants

Table 6-2 Total Polymers and PRR groups

	Total	Polymer Type (PRR groups)
Total polymeric substances placed on the market in the EU-27	145,697	
Total polymers meeting PLC criteria	62,734	
Total polymeric precursors manufactured for use only in industrial sites under Strictly Controlled Conditions	1,211	
Total polymeric precursors manufactured for use only in	23,533	

[80] Ibid footnote 62
[81] Ibid footnote 21

	Total	Polymer Type (PRR groups)		
industrial sites under Adequate Control Conditions				
Totals per PRR group		**Type 1 (<1,000 Da)**	**Type 2 (1,000-10,000 Da)**	**Type 3 (>10,000 Da)**
Policy Option 1				
CAS 1-10 tonnes	16,811	9,916	5,928	967
CAS 10-100 tonnes	22,499	16,461	5,281	757
CAS 100-1000 tonnes	11,107	5,449	4,235	1,422
CAS >1000 tonnes	5,380	1,268	2,491	1,621
Total	55,797			
Policy Option 2				
ECETOC	22,687	9,544	10,653	2,490

Table highlights the difference in the total number of polymer groups that may require registration according to the two policy options analysed in this study, with the ECETOC grouping approach under policy option 2 requiring fewer registrations. The grouping approach applied also leads to variation in the number of polymer groups in each polymer Type and thus impacts the information required during registration. This analysis reveals that **EU polymer manufacturing companies are estimated to experience an additional regulatory burden that would primarily apply** the first seven years from the introduction of REACH registration requirements for polymers. **Over this short period, regulatory burden is estimated to increase from 0.4% in the baseline to up to 2.5% and 1.9% of turnover in Policy Option 1: REACH SIR and Policy Option 2: ECETOC central scenarios, respectively.**

That is the direct result of an additional annualised regulatory burden of €1.6 and €1.2 billion each year over the 7-year period 2025-2031, against the baseline. This burden is subject to uncertainty in testing costs. These results correspond to the central scenario for testing costs under each of the Policy Options.

This additional regulatory burden would lead to an increase in operating expenditures when compared to the baseline. This additional burden would be partially mitigated by a reduction in the operating size of the business due to net product withdrawals that result from this increase in regulatory burden, considered in the following paragraphs. For Policy Option 1 (REACH SIR), the analysis suggests that operating costs would increase by 1.3% against the baseline for each year between 2025 and 2031, or €0.9 additional billion in OPEX per year over that period, in annualised terms. For Policy Option 2, the implementation of the ECETOC testing strategy is expected to increase operating costs by 0.9% against the baseline for each year over the same period, or €0.6 additional billion in OPEX per year.

Impacts on the portfolio of products, business size and, thus, sectoral turnover from the introduction of REACH registration requirements for polymers are only expected in cases where companies are not able to absorb the additional regulatory burden, i.e., where increases in regulatory burden negatively affect the economic viability of certain products.

Joint registrations are expected to be considered under polymer registration, but it is not yet clear how this would be facilitated as there is no clearly established substance identification mechanism for polymers. As such, consortia management costs have not been included in the economic analysis. On one hand, joint registration would reduce the number of registrations submitted, whilst on the other hand, it increases the burden on registrants due to SIEF management work. In addition, polymer modification by downstream users, leading to the manufacture of new polymeric substances, is not taken into account in this assessment.

The analysis for this study suggests that most of the surveyed companies would be able to absorb these new costs, with a few exceptions that would lead those products being withdrawn from the market. The potentially affected portfolio that falls into this exception would be equivalent to around 1.2% and 1.4% of the 2019 sector's turnover due to Policy Options 1 and 2 respectively. Even though the overall additional regulatory burden is larger for Policy Option 1, different numbers of PRR groups are affected by each policy option for each company, and that happens in a non-linear manner: for some companies, more PRRs arise from Policy Option 1, while for some others, more PRRs arise from Policy Option 2. As a result, in the surveyed sample, more

companies cannot afford the additional costs under Policy Option 2, but the aggregate costs are larger under Policy Option 1.

The affected companies, however, have reported that they would be able to implement some substitution and reformulation for around one third of this potentially affected portfolio of polymers. The remainder, that is the portfolio of products that could not be substituted and reformulated, would be withdrawn and their turnover lost when compared against the counterfactual. As a result, in **addition to increasing regulatory burden, the polymers sector in the EU-27 would be faced by turnover losses of 0.8% and 0.9% of the sector's turnover value under Policy Options 1 and 2 respectively, when compared against the baseline, and this result is driven by companies or product lines whose economic viability is affected by the regulatory costs.** If the polymers sector is unable to substitute and/or reformulate as indicated in their survey replies, which will rely on a favourable market response to the substituted and/or reformulated products, these direct losses could be higher and up to 1.2 to 1.4% of the sector's turnover.

Capital expenditure and R&D dedicated to substitution and reformulation strategies to recover some of this lost portfolio with alternative products would also be expected, involving activities such as research and development (R&D) and the adaptation of manufacturing processes, as reported by survey respondents. These effects, as mentioned, will be concentrated in the first seven years from adoption of the policy changes.

Based on these potential market losses against the baseline, **it is estimated that the sector's direct contribution to GVA would be €1.1 and €0.9 billion lower per year between 2023 and 2040, when compared to the baseline, under Policy Option 1 and 2, respectively**. These impacts are considered direct because they exclusively affect the EU polymers industry. **Such impacts would have knock-on effects along the supply chain (indirect effects) and the wider EU economy (induced effects), reducing the European GDP by €3.2 and €2.5 billion per year on average between 2023 and 2040**, when compared to the baseline.

In this context, it is estimated that 600 and 700 jobs, or 0.4% and 0.5% of the polymers sector's employment, would be lost by the end of 2040 against the baseline scenario, under Policy Options 1 and 2, respectively. If the polymers sector is unable to substitute and/or reformulate as indicated in their survey replies, which will rely on a favourable market response to the substituted and/or reformulated products, these direct employment losses could be higher. This net loss of jobs takes into account that additional staff would also be needed to develop all the new activities that would be undertaken to meet the new registration requirements, as reported by survey respondents. These additional jobs are estimated in around 450 overall, although they are expected to be temporary positions, due to the transitory nature of the registration activities for polymers**.**

Table below summarises some of these impacts on key business and economic indicators against the baseline and across the two Policy Options, using the central estimates only.

Table 6-3 Annualised impacts on selected business and economic indicators of the EU polymers manufacturing sector, against the baseline scenario (%) – central scenario

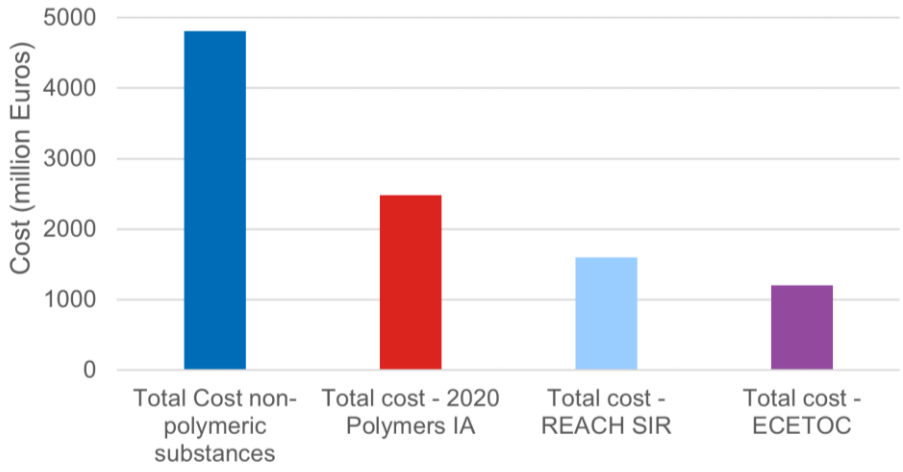
Themes (business or economic indicators)	Policy Option 1 (REACH SIR)	Policy Option 2 (ECETOC Grouping and Testing)
Turnover (first order effects)	A loss of €580 million per year on average against the baseline over the 2023-2040 period	A loss of €660 million per year on average against the baseline over the 2023-2040 period
Total GVA contribution (*direct, indirect, induced*)	A loss of €3.2 billion per year on average against the baseline over the 2023-2040 period	A loss of €2.5 billion per year on average against the baseline over the 2023-2040 period
Regulatory burden	An additional annualised burden of €1.6 billion each year over a seven-year period	An additional annualised burden of €1.2 billion each year over a seven-year period

Themes (business or economic indicators)	Policy Option 1 (REACH SIR)	Policy Option 2 (ECETOC Grouping and Testing)
Total employment contribution (*direct, indirect, induced*)	1,500 fewer jobs, on average, when compared to the baseline in any given year	1,700 fewer jobs, on average, when compared to the baseline in any given year

More than **90% of the polymer manufacturing and importing companies** surveyed expect that the introduction of REACH polymer registration requirements **will affect their competitiveness negatively or very negatively**, and no company reported expecting a positive impact. These impacts are not likely to be captured in full in the estimates summarised in Table . Regarding the testing activities required for registration, more than half of polymers companies surveyed for this study lack in-house laboratory facilities and, even the ones which do have such facilities consider that they would be unlikely to meet all of their testing needs due to limitations of testing capacity in the EU. Hence, there will likely be delays in the attainment of registration of all PRR in the sector once the polymers registration requirements are adopted. This delay has not been included in the analysis due to a lack of clarity as to when this could be resolved. Therefore, the analysis assumes that test capacity is sufficient for all testing activities to be developed over a span of seven years.

The cost of the two policy options considered in this Study have been compared with the total cost of REACH registration of non-polymeric substances (current REACH registration requirements) and the estimated cost of polymer registration in the 2020 study (Figure 6-2). As no formal decision has been made on the fees for polymer registration, current ECHA fees for REACH registration have been carried forward in this assessment, with no fee for notification. The current REACH registration requirements are approximately 3x higher than those estimated for Policy Option 1: REACH SIR and approximately 4x higher than Policy Option 2: ECETOC. The 2020 study estimate of the cost of polymer registration are around 1.5x higher than Policy Option 1: REACH SIR and 2x higher than Policy Option 2: ECETOC in this Study. Although the total costs of polymer registration may be lower than for non-polymeric substances, this assessment is associated with a high level of uncertainty and it is expected that registrations will be more complex.

Figure 6-2 Comparison of the actual and estimated costs of REACH registration (current requirements and polymer registration)



The results of this assessment highlight that introducing polymers registration requirements would lead to very significant increases in the regulatory burden faced by polymers manufacturers under Policy Option 1: REACH SIR– almost 6 times higher than the baseline's (no polymer registration) burden on average over the 7-year period over which costs are expected to be incurred, in the early years from adoption. Policy Option 2: ECETOC does also produce significant, albeit lower, increases in regulatory burden on aggregate, being around 4 times higher than the baseline's burden in the immediate seven years from adoption.

This burden would likely result in some reductions in the manufacturing and/or use of polymers currently on the market in the EU-27, with some withdrawal of polymeric products and associated turnover losses against the baseline. These reductions would be higher if companies are unable to absorb the additional regulatory burden, with more of their products becoming unviable from an economic perspective.

To mitigate these negative impacts on industry resilience, support could be provided to the polymers industry through a clear implementation roadmap and the use of additional mechanisms be that financial, regulatory or additional time to respond to any policy changes, which could facilitate innovation and allow for new, more sustainable products to be brought to the market. The use of a phased approach to implementation, as was done for non-polymer substances previously could aid in mitigating economic burden but this would require further investigation.

It should be noted that potential subsequent regulatory management of polymers (e.g. restrictions) has not been accounted for in this exercise e.g. the extension of the GRA. Any regulatory management following registration of polymers would result in additional business impacts, but it is not possible to estimate such impact presently. Further analysis would be needed to assess whether the estimated costs to the EU-27 polymers sector and the wider economy could be outweighed by any impacts of the proposed policy options on health, the environment and other economic impacts not considered in this study.

Laboratory Capacity

As was noted above, tests may require refinement for polymers. The input collected from 11 CROs shows that testing capacity could be a rate-limiting factor. Capacity for testing varied greatly between CROs and tests. The range of capacity per type of information requirement is provided in Table 6-4. Large variations in test capacity are largely based on the type of test e.g. *in vivo* testing (particularly long-term or repeat dose) have lower laboratory capacity than *in vitro/ in chemico* tests. Although the sample of respondents does not represent the entire capacity of laboratories in Europe**, it can be seen from the capacity reported that it may be difficult to have all PRR groups tested and registered within the first few years of implementation of polymer registration, particularly if the REACH SIR are taken forwards**. Polymers are not like non-polymer substances in that very few have been tested for (eco)toxicological endpoints and so there is not an existing database of results to call upon. This means that the impacts from testing costs of polymer registration would be felt upfront.

Table 6-4 Laboratory capacity

Type of Information Requirement	Currently perform (respondents n=11)	Capacity per year (number of tests)	In chemico/ in vitro performed (average)	In vivo performed (average)
Physico-chemical	0-8	12-56	-	-
Environmental Fate and Behaviour	0-7	4-72	-	-
Ecotoxicology	0-6	4-25	12	8
Toxicology	0-3	5-375	101	28

7. QUALITATIVE ASSESSMENT OF THE ESSENTIAL USE DEROGATION IN THE CONTEXT OF THE REACH MICROPLASTICS RESTRICTION CASE STUDY

This section seeks to understand and compare the current approach to formulating derogations under the restriction process of REACH with the proposed essential use derogation approach as described in the CSS.

To assess how this change of derogation approach may impact future restrictions the restriction of intentionally added microplastics, proposed in 2017, has been used as an example restriction. This is one of the largest restrictions under REACH to date. Bearing this in mind and considering the increased focus on grouping substances from a regulatory perspective[82], this restriction has been selected as a suitable example through which to compare the future use of the essential use derogation approach under the REACH Restriction process. The essential use concept will be applied also under the extension of the GRA and under REACH Article 68(2) however this has not been evaluated here. The two REACH Restriction approaches, current and future including the essential use concept, have been compared with a focus on the following components:

- Information requirements
- Derogation assessment process
- Resulting derogation

Due to the hypothetical nature of the REACH restriction process including the essential use concept and the current lack of essential use criteria from the European Commission, the results presented here are qualitative and based on available literature and expert judgement. This study focuses on the efficiency, clarity and regulatory outcomes of the essential use derogation approach, the costs or benefits to the protection of human health or the environment are not discussed or evaluated here.

7.1 ESSENTIAL USE CONCEPT

One of the key aims of the CSS is for the EU to strive for a toxic-free environment. By allowing the use of harmful chemicals only when they are deemed essential to society and provided there is no alternative, the Commission intends to increase the protection of human health and the environment across EU chemicals legislation. The CSS stresses the need for consistent approaches across legislation for ease of compliance and efficiency, thus the criteria for essentiality are expected to be uniform across legislation[83]. The concept of essential use is also intended to contribute to the Commission's aim to streamline chemicals legislation and speed up the response to emerging contaminants by simplifying the decision time required for risk management, whilst taking into consideration the needs for achieving the green and digital transition.

The CSS provides little detail on the boundaries or on the criteria for uses essential for society and the application of an essential use definition is the subject of an ongoing Commission Impact Assessment. The scope of essentially has been described in the CSS as:

> "*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*"[84].

The text also references the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol)[85] as an established example of the essential use concept. However, the application of the concept across the entirety of the EU chemical industry would require adjustments from the Montreal Protocol

[82] As indicated under the actions regarding the GRA in 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 Final. Available from: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

[83] Ibid footnote 12

[84] Ibid footnote 12

[85] United Nations (1987) *The Montreal Protocol on Substances that Deplete the Ozone Layer.* Available from: The Montreal Protocol on Substances that Deplete the Ozone Layer | Ozone Secretariat (unep.org)

approach. Prior to the publication of the CSS, Cousins et al.[86] discussed the application of the concept as an exception to a ban on PFAS. Cousins et al. also based their discussions on the Montreal Protocol definition, further developing this by defining what the boundaries of essential are through substances that are "*non-essential*" and "*substitutable*". Their article also stressed the need for essentiality to evolve over time as societal needs change.

The CSS specifically states that the concept of essential use will be used in conjunction with the regulation of endocrine disrupting chemicals, the REACH restriction of PFAS, the most harmful of Substances of Concern in consumer products and be implemented in combination with the extension of the GRA. REACH is currently under review with a Commission Impact Assessment expected by the end of 2022[87]. The derogation for essential uses is expected to be included as part of the revisions to REACH including the extension of the GRA, and the revision of the restriction and authorisation processes.

Concept Development

In the Annex of the CSS, the Action Plan[88] states 2021-2022 as the expected period in which the European Commission will determine the criteria for essential use. In the time since the publication of the CSS there have been calls for clarification[89] from industry and NGOs, and a number of articles[90,91] focused on the application of essential uses in chemicals legislation generally and specifically to groups of substances. Some of the observations have focused on who should be responsible for these decisions and how to define essentiality according to the following aspects[92]:

- how to account for quality of life;
- how to mitigate subjective judgements;
- how to include environmental considerations;
- how to evolve with society's needs;
- how to accurately define what is necessary for the functioning of society.

[86] I. T. Cousins, G. Goldenman, D. Herzke, R. Lohmann, M. Miller, C. A. Ng, S. Patton, M. Scheringer, X. Trier, L. Vierke, Z. Wang and J. C. Dewitt (2019) The Concept of Essential Use for Determining When Uses of PFASs Can Be Phased Out, *Environ. Sci. Process. Impacts*, 2019, **21**, 1803 —1815

[87] Ibid footnote 61

[88] European Commission (2020) *Annex to the 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 Final. Available from: EUR-Lex - 52020DC0667 - EN - EUR-Lex (europa.eu)

[89] Cefic (2020) *Defining Essential Use Of Chemicals – What Is At Stake?* Available from: Defining essential use of chemicals - what is at stake? - cefic.org. AmCham EU (2020) *REACH Restriction: Essential use criteria in the context of socio-economic impact analysis when unacceptable risk is demonstrated.* Available from: http://www.amchameu.eu/system/files/position_papers/pfas_essential_use_paper_-_final.pdf . ClientEarth, (2021). *Comments on "CA_61_2020_Essential uses".* Available from: http://files.chemicalwatch.com/56%20-%20ClientEarth-comments-CA-61-2020-essential%20use.pdf

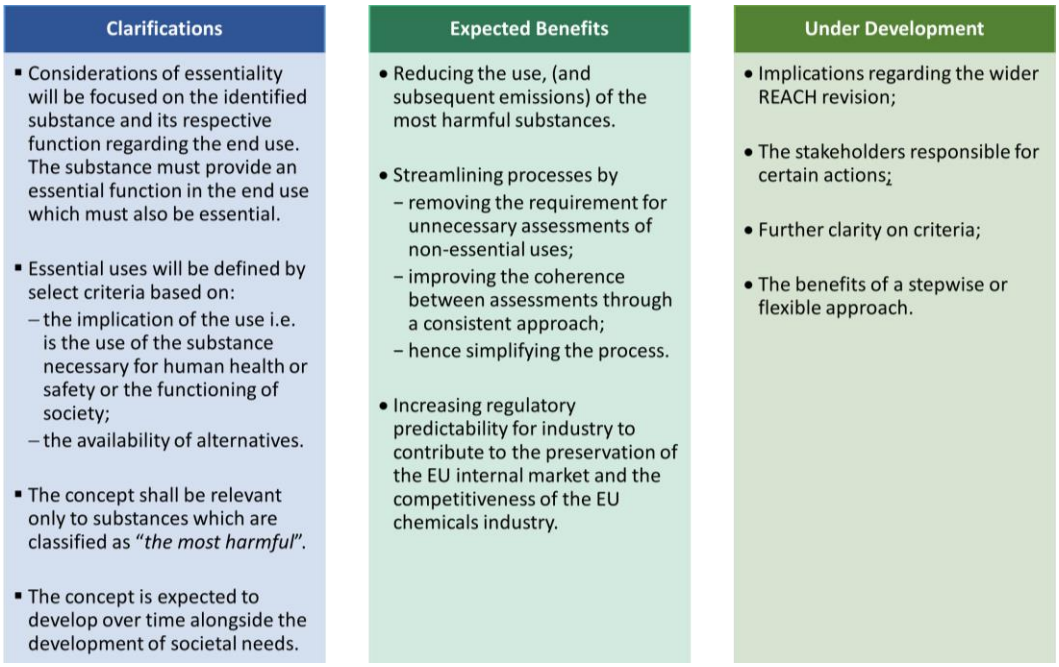
[90] Montfort, J (2021) *The Concept of Essential Use to Regulate Chemicals: Legal Considerations*, International Chemical Regulatory and Law Review, Volume 4, Issue 1 pp. 9 – 20.

[91] 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. Cambridge University Press, 10(1), pp. 159–187. doi: 10.1017/S2047102521000042.

[92] European commission (2022) Stakeholder Workshop on the concept of 'Essential uses'. Available from: Stakeholder workshop on the concept of 'Essential uses' (europa.eu)

In March 2022 a stakeholder workshop supporting the Commission in developing an essential use concept (The Essential Use Workshop)[93] took place to gather information for the Commission Impact Assessment. Discussions focused on clarification and the implementation of the concept under current chemicals legislation with the aim to gather views on multiple aspects of the concept as summarised in Figure 7-1.

Figure 7-1 A summary of the feedback and clarifications discussed in The Essential Use Workshop.



Source: Adapted from the Workshop Report on Supporting the Commission in developing an essential use concept[94]. These are direct contributions from stakeholders present at the workshop and not conclusions from this study.

The implementation of the concept across multiple pieces of EU chemicals legislation was discussed, with a focus on the use of the concept under REACH. With the Commission's aim to provide a "*simplified, systematic criteria for assessing derogations from restrictions and authorisation proposals*" a stepwise approach was proposed including screening steps, aiming to speed up the decision-making process[95]. This stepwise proposal was met with some criticism in The Essential Use Workshop with several stakeholders considering a screening process as unapplicable for the assessment of alternatives[96]. The process and effectiveness of the screening steps will be discussed in Section 7.3 The Comparison of approaches.

7.2 SCOPE OF CURRENT MICROPLASTICS RESTRICTION PROPOSAL

The restriction of intentionally added microplastics is one of the largest REACH restrictions to date with respect to the restriction scope and the implications[97]. The Annex XV report[98] to the REACH restriction states that polymers, covered by Article 3(5) of Regulation (EC) No 1907/2006: "*shall not be placed on the market as a substance on its own or in a mixture as a microplastic in a concentration equal to or greater than [0.01] % w/w*". Microplastics serve a multitude of functions across many industries, the main uses discussed in the Annex XV report are displayed in Figure 7-2.

[93] Ibid footnote 92

[94] Wood E&IS GmbH (2022) Workshop Background document. Available from: Background Document

[95] Ibid footnote 94

[96] Ibid footnote 94

[97] European Parliament (2021) Parliamentary questions, Answer given by Mr Breton on behalf of the European Commission Question reference: E-003388/2021. Available from: Answer for question E-003388/21 (europa.eu)

[98] ECHA (2019) Annex XV Restriction Report, Proposal for a Restriction. Available from: Registry of restriction intentions until outcome - ECHA (europa.eu)

Figure 7-2 A selection of the main uses and functions of intentionally added microplastics

Source: Adapted from the Annex XV Restriction Report[99].

Multiple derogations and transitional periods were proposed in the original restriction dossier and additions and adjustments were made following the opinions from RAC and SEAC. Most of the derogations were proposed in the original dossier resulting in a substantial information burden on the dossier submitter (in this case ECHA). Also, the majority of the derogations were subject to discussion in the final opinion documents from RAC and SEAC resulting in a substantial burden from the derogation aspect of the Restriction proposal.

It should be noted that not all REACH restrictions in the past have included a large selection of derogations like this, but the breadth included in this restriction for microplastics reflects how ubiquitous these substances are across industries and how many diverse (groups of) polymeric substances this entry covers. The derogations have been used to focus the restriction on the sectors or uses of concern[100].

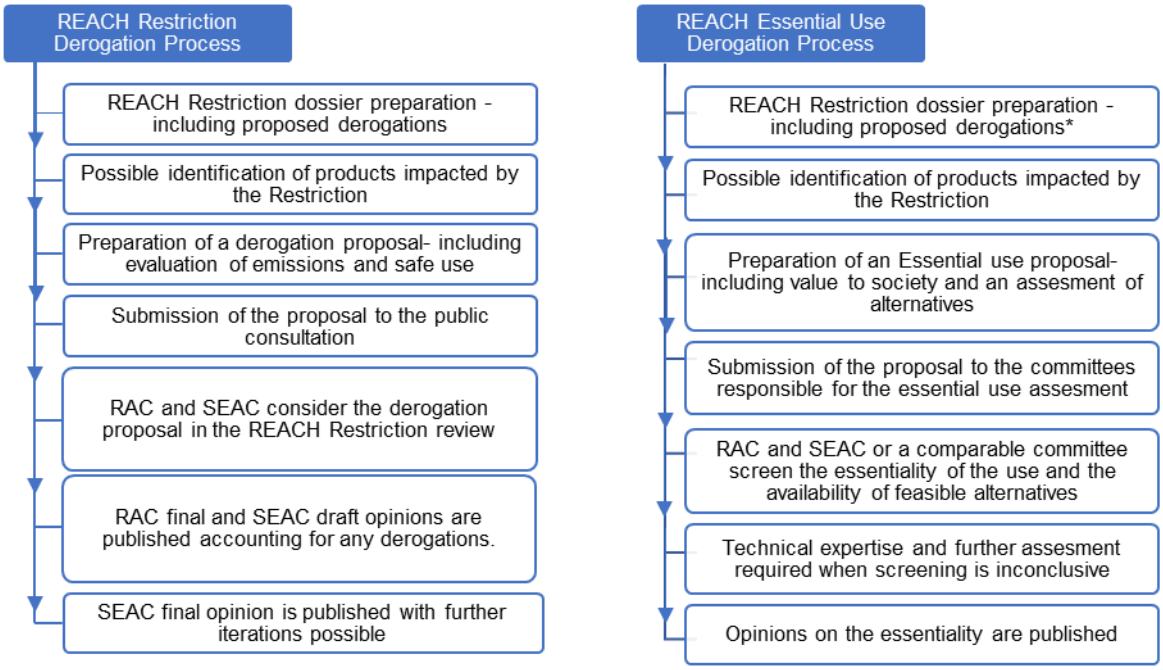
7.3 COMPARISON OF APPROACHES

The REACH Revision is yet to be published and therefore we have assumed a similar restriction process will be retained (Figure 7-3), but the derogations and transitional periods will include the concept of essential use. These assumptions are supported by the 45th Meeting of Competent Authorities for REACH and CLP (CARACAL) which took place in July 2022 and discussed the options concerning the revision of REACH. This included the implementation of the essential use derogation in combination with derogations for uses resulting in no unacceptable risk under Article 68(1). Article 68 of REACH employs the SRA approach under Article 68(1) and the GRA under Article 68(2), for more detail on risk management approaches see Section 4.1.2. Both approaches are expected to include essential use considerations, however this study focuses on Article 68(1) and compares the use of the essential use concept under the SRA approach only.

[99] Ibid footnote 98

[100] ECHA (2020) Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on intentionally-added microplastics. Available from: https://echa.europa.eu/documents/10162/a513b793-dd84-d83a-9c06-e7a11580f366

Figure 7-3 Comparison of the two derogation processes (for an Article 68(1) restriction).



Source: Ricardo and adapted from the ECHA Restriction Process.

Proposal information requirements

Currently derogation proposals may be included in the original restriction dossier, proposed later in the process by respondents to the public consultation, or by SEAC and RAC when reviewing the dossier. In Table the information requirements of each approach have been estimated and rated on a scale of 1 to 10.

Table 7-1 Ratings of the information burden on the dossier submitter under each process.[101]

Current derogation information requirements	Burden	Essential use derogation information requirements	Burden
The substance concentration/quantity	2	All intended uses	7
All emissions throughout the product lifecycle	7	The substance's function in the intended use	3
Actions taken to minimise exposure and emissions	7	The substance's necessity for human health or safety	7
Analysis of alternatives	9	The substance's criticality for the functioning of society	7
Socioeconomic impacts of the proposed restriction	8	An analysis of alternatives; effectiveness, cost, human health and the environment.	9

From the estimations in Table the approaches are expected to be comparable in the information they require (with both approaches totalling 33). These scores will be flexible to the derogation proposed, for example if an organisation applied for a derogation for a specific use of the restricted substance then both the possible emissions throughout product life cycle (under the current derogation proposal) and the list of intended uses

[1] ECHA (n/a) Restrictions Process, Available from: Restrictions process - ECHA (europa.eu). Represents information easily obtainable or expected to already be known and 10 represents information that requires extensive research and expert knowledge. These estimations are based on the details provided in the Microplastics Background Document and the original restriction dossier. The expected demands of the essential use derogation procedure have been estimated based on literature and stakeholder views from The Essential Use Workshop.

[101] The average informational burden of each aspect of the derogation proposal has been estimated based on the review of past dossiers and considerations from the Essential use workshop. ECHA (2022) Substances restricted under REACH. Available from: Substances restricted under REACH - ECHA (europa.eu) and Wood E&IS GmbH (2022) Workshop Report. Available from: Essential Use Workshop Report final.pdf (europa.eu)

(under the essential uses derogation proposal) would be a significantly smaller burden. As with medical applications or substances serving functions critical for safety, these uses are expected to require minimal proof of essentiality as the benefits from medical and safety functions are implicit. It can therefore be predicted that sectors not clearly linked to human health or safety may face a larger information burden during the derogation process.

One area of each derogation proposal which is expected to be a substantial burden is the analysis of alternatives. Many stakeholders, industry and Member State Authorities have highlighted this as an information intensive process which may weigh heavily on the essential use derogation process[102]. However this aspect is already under consideration in the derogation procedure and included in the reviews by RAC and SEAC. Their focus on this aspect has been criticised[103] and is repeatedly included as an area for improvement in the Recommendations from RETF, first mentioned in 2016 and stated as ongoing in the 2020 publication [104]. This analysis is expected to be burdensome and may lead to delays or increased costs associated with the derogation procedure.

Stakeholders have commented that gathering information on all the expected uses of the substance (under the essential use derogation process) could be a significant burden due to complex supply chains. However, this could be comparable to the volume of information required to understand emissions during product lifecycle (required under the current approach) and hence these aspects of each process have been given the same score of 7/10. Although the information burden is expected to be comparable, as has been stressed in the CSS and The Essential Use Workshop, the burden is expected to be on the applicant of the derogation. In the case of the restriction of intentionally added microplastics, the dossier submitter (ECHA) included a number of derogations in the original dossier to make a comprehensive case for the restriction. Adopting the essential use derogation would aim to reallocate this burden from the restriction dossier submitter to the derogation applicant. Authorities may be required to provide information when using the concept to confirm or reject a derogation proposal although this is expected to be primarily sourced from the derogation proposals submitted by the applicant. A redistribution of burden is not necessarily a benefit overall. Currently the dossier submitter has access to information after calls for evidence and the consultation on the restriction report. Industry may be limited to the information they have available in-house or they would need to create a consortium to gather sufficient supply chain information to meet the data needs of an essential use derogation without contravening competition law. As such, industry may struggle to gather sufficient data in order to be able to demonstrate essentiality in the timeframe allowed, increasing the possibility that uses may not be included in the Committee assessment.

As many REACH Restrictions are now focused on groups of substances, it can be expected for derogations to also cover groups which will add complexity to the analysis of essentiality and the assessment of alternatives. The information burden for derogations for uses which are considered clearly essential (medical uses) are expected to be reduced partly because considerations of life cycle emissions would not be a priority, although alternatives would still require assessment. For uses with a less obvious connection to human health/safety or the functioning of society the derogation burden could increase and become more complex, this could lead to certain sectors being impacted more than others. In addition, it has been noted that SMEs may struggle to provide the information required as they do not have the same level of resources available to them as larger organisations[105].

The derogation assessment processes

Under the proposed essential use concept, the derogation applicant will need to consider the following questions and address these in the derogation reasoning for the Committees to review:

- Is the function of the substance necessary for health and or safety?
- Is the function of the substance critical the functioning of society?
- Are there alternatives which are acceptable when considering human health and the environment?[106]

[102] Ibid footnote 94

[103] Ibid footnote 9

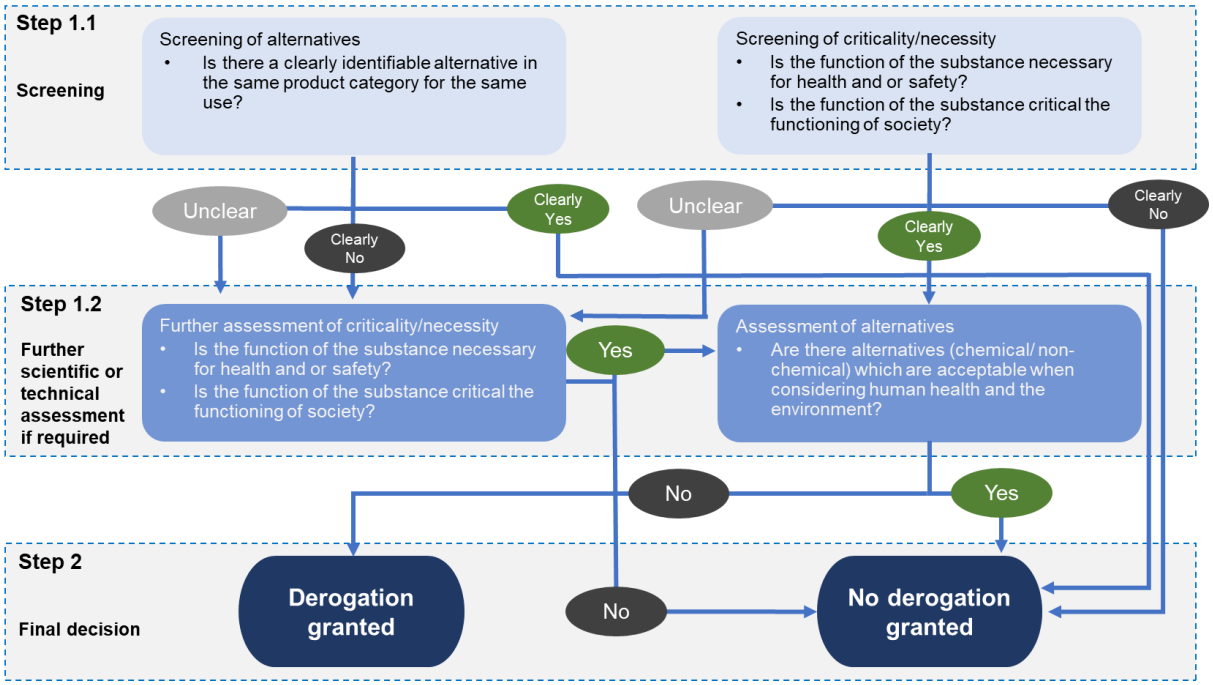
[104] ECHA (2020) Recommendations of the Task Force on Restriction Efficiency, Available from: https://echa.europa.eu/documents/10162/13641/report_task_force_o

[105] Ibid footnote 94

[106] Ibid footnote 94

The responsible Committee will at first screen the derogation reasoning according to these questions. If the screening step is not conclusive then a technical or scientific review is required (Step 1.2 in Figure 7-4).

Figure 7-4 Stepwise application of the essential use concept to the REACH restriction process.



Source: Adapted from the Workshop Report on Supporting the Commission in developing an essential use concept[107]. The process may require 2 or 3 steps depending on the complexity of the derogation application. Note: there are multiple variations of this scheme under consideration at the time of publication.

The stepwise approach aims to streamline the process, a clear negative response to the screening criteria would not require further considerations from the responsible Committees. This screening step may also offer clarity to the proposal submitters on their chance of success, if the criteria are clear this could reduce the number of derogation application received and reduce the number which would require in-depth analysis. In addition, considerations of the essentiality in the restriction proposal according to these screening steps could clarify which uses would not be considered essential, saving both the applicant and Committees valuable time.

In contrast to the aims of the screening and stepwise approach of this derogation process, it can be expected for the screening of alternatives to be complex. If essentiality is clearly defined by the Commission a decision may be made on this aspect depending on the relevance of the use, clear decision making is unlikely to be the case with the screening of alternatives. The assessment of alternatives is a burdensome process which is highly specific to the substance and the use under examination, in some cases there may be obvious alternatives available however the analysis of comparable functionality, availability and socioeconomic viability of alternatives is unlikely to be obvious from just a screening step. Based on the views of stakeholders on the analysis of alternatives and the expertise required for this process it can be expected for the screening step here to not provide a substantial benefit to the efficiency of the derogation process.

The proposed process may also have implications for the information burden as the information needed for the screening step could be adjusted. With a reduced proposal required initially and a comprehensive derogation proposal requested if needed for Step 1.2. This could relieve the information burden on the applicant and speed up the processing of derogation proposals. Nevertheless, this approach could lead to additional delays when requesting further information for Step 1.2, which could negate the original benefit.

When considering the implementation of an essential use derogation under the REACH restriction process there are opportunities, such as this stepwise method, that could offer the responsible Committees a fast-track process to minimise their obligatory considerations, especially regarding risk and the associated

[107] Ibid footnote 94

socioeconomics. These screening steps would not be as appropriate under the current RAC and SEAC assessment methods as these require more detailed approaches and provide fewer binary outcomes.

The resulting derogations

The restriction of intentionally added microplastics applies to all microplastics that fit the definition across all sectors. Specific derogations have been applied to certain sectors, technical functions or to refine the scope of the restriction. During the review of the restriction dossier the scope received a high level of scrutiny from RAC and SEAC because of the breadth of the restriction. Derogations, 3.a-c of the restriction proposal, are not directly comparable to an essential use derogation as they are not specific to the technical function but are intended to focus the scope of the restriction on the concerns raised.

3.a *Natural polymers that have not been chemically modified (other than by hydrolysis).*
3.b *Polymers that are (bio)degradable, as set out in the criteria in Appendix X of the restriction.*
3.c *Polymers with solubility > 2 g/L*

RAC stated in their opinion that these derogations are important to refine the scope of the restriction, and it can be expected for future REACH restrictions of a similar magnitude to require comparable refinements[108]. Derogations 5.a-c focus on uses which lead to minimal emissions due to containment, transformation, and disposal control. These are considered to be "safe uses".

5.a *Substances or mixtures containing microplastic where the microplastic is both (i) contained by technical means throughout their whole lifecycle to prevent releases to the environment and (ii) any microplastic containing wastes arising are incinerated or disposed of as hazardous waste.*
5.b *Substances or mixtures containing microplastics where the physical properties of the microplastic are permanently modified when the mixture is used such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a).*
5.c *Substances or mixtures containing microplastics where the microplastic are permanently incorporated into a solid matrix when used.*

The essential use concept does not account for safe uses however under the proposed revisions of the REACH restriction process described in the 45th meeting of CARACAL derogations based on uses resulting in no unacceptable risk will be permitted.

The derogations included under paragraph 4 and the transitional periods under paragraph 6 are sector or use specific derogations. Some of these derogations are granted based on the function that intentionally added microplastics play in the use. However, some of the derogations (

Table) have been included to prevent the double regulation of substances via multiple pieces of EU chemicals legislation. Avoiding double regulation is not a factor of the essential use concept although the CSS discusses reinforcing REACH as one of the "cornerstones" of the EU's chemical legislation which may impact the way in which REACH restrictions accommodate or do not accommodate overlapping legislation. Also, if the essential use derogation is introduced across all EU chemicals legislation, then the derogations would be harmonised across legislation potentially removing any conflicting decisions and the requirement for derogations such as these.

Table to Table below all state the derogations included under the restriction and their possible result after the initial screening step as shown in Figure 7-4. Decisions confirming essentiality in the initial screening step would then lead to an assessment of alternatives. If "No" is stated as a response for the screening of essentiality in the table below then the derogation application is expected to be rejected at the screening stage and no further review is expected. If any of the responses during the screening stage are "Unclear" then further analysis is expected to be required with expert input. Only if essentiality is confirmed (response "Yes" in the table below) and there are no acceptable alternatives (response "No" in the table below) can a derogation be granted from the screening stage. As noted in previously in Section 7.3, it is not expected for the screening of alternatives to be straight forward and thus derogations granted from the screening step alone would be rare.

[108] For example the REACH Restriction of per- and polyfluoroalkyl substances (PFAS), European Commission, n/a, PFAS. Available from: PFAS - Chemicals - Environment - European Commission (europa.eu)

Table 7-2 Estimation of the results of Step 1.1 of the essential use derogation process, derogations 4.b-d.

Para	Proposed Derogation	Explanation	Necessary for health and or safety	Critical for the functioning of society	Available acceptable alternatives	Next steps
4.b	*Medicinal products for human or veterinary use*	To avoid double regulation.	Yes	Yes	Unclear	Further assessment - Alternatives
4.c	*Substances or mixtures that are regulated under Regulation (EC) No 2019/1009*	To avoid double regulation. [109]	Unclear	Unclear	Unclear	Further assessment
4.d	*Substances or mixtures containing food additives*	To avoid double regulation.	No	Unclear	Unclear	Further assessment

A further subsection of sector specific derogations have been included in the restriction because of the unintentional inclusion of microplastics (Table). These derogations could be described as a refinement of the scope as the restriction is focused on *intentionally* added microplastics, however it is unlikely these would classify for an essential use derogation when analysed under Step 1.1. Both would be expected to require further in-depth analysis of the use and implications for the functioning of society.

Table 7-3 Estimation of the results of Step 1.1 of the essential use derogation process, derogations 4.f-g.

Para	Proposed Derogation	Explanation	Necessary for health and or safety	Critical for the functioning of society	Available acceptable alternatives	Next steps
4.f	*Sludge and compost.*	These can unintentionally contain microplastics	No	No	n/a	Derogation denied
4.g	*Food and feed.*	These can unintentionally contain microplastics	No	Unclear	n/a	Further assessment

The remaining derogations and transitional periods are comparable with the essential use concept and in the table below, the initial screening steps proposed have been employed[110]. The considerations under Step 1.1 are designed to be answered based on the information in the derogation proposal without the need for additional information or analysis. Therefore here we have reviewed the original dossier information to estimate the results of Step 1.1 of the essential use derogation process, as shown in Table . Any decisions which are not clear from the screening step will progress to further technical or scientific analysis (step 1.2 of Figure 7-4) which has been modelled as comparable in burden to the current approach used by RAC and SEAC in the REACH Restriction process. Many of the transitional periods in Table allow industry time to switch to alternatives, here it has been considered that if alternatives are available then an essential use derogation will not be permitted. However, it is not clear if transitional periods will be within or external to the scope of the essential use concept under the REACH Restriction process.

[109] The Fertilising Products Regulation includes provisions to phase out the use of non-biodegradable polymers in EU Fertilising Products

[110] Ibid footnote 94

Table 7-4 Estimation of the results of Step 1.1 of the essential use derogation process.

Para	Proposed Derogation	Explanation	Necessary for health and or safety	Critical for the functioning of society	Available acceptable alternatives	Next steps
4.a	*Substances or mixtures containing microplastics for use at industrial sites.*	To prevent regulation on industrial uses.	Unclear	Unclear	Unclear	Further assessment
4.e	*In vitro diagnostic devices*	Based on socio-economic considerations.	Yes	Unclear	Unclear	Further assessment
4.h.a	*Granular infill used on synthetic sports surfaces where risk management measures are used*		No	No	Yes	Derogation denied
6.a	*EiF for cosmetic products (as defined in Article 2(1)(a) of regulation (EC) No 1223/2009) and other mixtures containing microbeads.*	Alternatives are widely available and a voluntarily phase out of microbeads has already started.	No	No	Yes	Derogation denied[111]
6.b	*EiF + 2 years for medical devices as defined in regulation (EC) 2017/745 and in vitro diagnostic medical devices*	To allow time to implement the means technically to contain microplastics.	Yes	Unclear	Unclear	Further assessment
6.c	*EiF + 4 years for 'rinse-off' cosmetic products*	Time for reformulation and transitioning to alternatives.	No	No	Yes	Derogation denied
6.d	*EiF + 5 years for detergents*	Time for reformulation and transitioning to alternatives.	No	Unclear	Yes	Derogation denied
6.e	*EiF + 5 years for fertilising products not regulated under Regulation (EC) No 2019/1009 that do not meet the requirements for biodegradability*	Time for the development of biodegradable polymers with comparable functionality.	No	Unclear	Yes	Derogation denied
6.f	*EiF + 8 years plant protection products Regulation (EC) No 1107/2009 and Regulation (EU) 528/2012.*	Time for the development of biodegradable polymers.	No	Unclear	Yes	Derogation denied
6.h	*EiF + 5 years for other agricultural and horticultural Regulation (EC) No 1107/2009 and Biocides Regulation (EU) 528/2012.*	Time for the development of biodegradable polymers with comparable functionality.	No	Unclear	Yes	Derogation denied
6.g	*EiF + 6 years for 'leave-on' cosmetic products (as defined in regulation (EC) No 1223/2009).*	Time for reformulation and transitioning to alternatives.	No	No	Yes	Derogation denied

Of the fourteen proposed derogations (3.a – 5.c):

- six derogations are not directly comparable to the essential use concept (paragraphs 3 and 5);
- two derogations could be expected to be denied after screening step 1.1;
- five derogations would require Step 1.2 - further technical or scientific assessment of essentiality and alternatives after screening step 1.1;
- and one derogation could be expected to be granted depending on assessment of alternatives (medicinal products, if there are no alternatives).

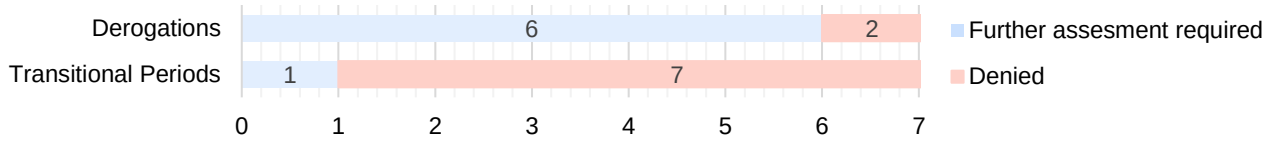
[111] This is consistent with the current proposal conclusion which states that cosmetics containing microbeads must comply from the day of Entry into Force.

The proposed transitional periods were included in the most recent Annex XV Restriction Report[112] to allow for the development of comparable alternatives and to reduce the socioeconomic impacts. However, the Background Document discusses alternatives which are already in development and the concept of essential use is not expected to focus on socio-economic impacts therefore many of these may not be granted under the essential use concept[113].

Of the eight proposed transitional periods (6.a - 6.g):

- One transitional period could be expected to be permitted after screening Step 1.1;
- Six transitional periods could be expected to be denied after screening Step 1.1; and
- One of the transitional periods would require further analysis under step 1.2.

Figure 7-5 Summary of the results of Step 1.1 of the proposed essential use derogation process.



The derogations deemed not to be comparable have not been included.

It should be noted that these outcomes are based on screening step 1.1 solely and are not the final expected conclusions of the derogation procedure. Many derogations are expected to require further assessment and in particular a further, in-depth, assessment of alternatives. For a derogation to be granted according to the proposed process in Figure 7-4 the derogation must progress through Step 1.1 and Step 1.2 if required. Although this analysis is not conclusive on the final outcomes of the essential use derogation process the outcomes of Step 1.1 listed in

Table to Table above are informative of the benefits and disadvantages of the proposed essential use derogation process, especially concerning the efficiency of a stepwise screening process.

7.4 CONCLUSIONS

Efficiency – time and resources

The information requirements under the current process are cumbersome and have received criticism, however this is not expected to change with the implementation of the essential use concept. There would be some gains and some losses as some of the burden would be transferred to the new processes being introduced. The information required for the derogation of uses which are considered essential may be reduced as life cycle emission considerations will not be a priority. Also, a similar argument can be made regarding the Committee's considerations of uses that are clearly non-essential which will lead to rapid decision making and reduced burden. For example, the time spent discussing the use of microplastics in infill in sports fields could have been avoided under the essential use process, because the derogation may have been denied after Step 1.1. In contrast, **for uses with an ambiguous connection to human health/safety or the functioning of society the derogation proposal requirements and decision-making process could increase and become more complex leading to delays and increased burden**.

From the case study analysis of the proposed derogations, 75% of the applicable derogations (8 total derogations deemed as applicable under paragraph 4) required further assessment under the essential use concept. The remaining derogations (25%, 2 out of the 8) have been predicted to have conclusions after Step 1.1 of the process (either granted or denied), which may have improved the efficiency of the restriction process. In this study the use of the screening step has proven effective once due to the availability of alternatives and once for considerations of essentiality, this is based on the understanding of the essential use concept as of September 2022. When implemented, decisions based on the essential use concept may prove more complex or more straight forward depending on the definition and this will impact the benefits of the screening process. The use of a screening step may also benefit the derogation applicant as further information may only be required if the screening step is inconclusive, although this is dependent on the how often the screening step

[112] Ibid footnote 98

[113] ECHA (2020) Background Document, to the Opinion on the Annex XV report proposing restrictions on intentionally added microplastics. Available from: Registry of restriction intentions until outcome - ECHA (europa.eu)

leads to a clear conclusion. This could reduce the burden on the applicant in addition to speeding up the process, allowing the applicant to redirect focus if needed on to mitigating the impact of the restriction via other methods. **The benefits from this staggered information requirement approach may be outweighed if delays occur when requesting further information from the derogation applicant.**

However, the screening of alternatives is not expected to streamline the process as the assessment of alternatives is highly specific to the use and the substance, resulting in the need for expertise and time. Therefore the use of a screening step here is unlikely to be conclusive. If the decision from Step 1.1 rests on the analysis of alternatives, the stepwise screening process is not expected to result in a faster conclusion compared to the current approach.

The derogation applicants (industry primarily) are expected to be the main provider of the derogation supporting data. **This redistribution of burden will alleviate the pressure on public authorities however this may hinder the accuracy of the process**. Currently the dossier submitter has access to the information from the calls for evidence and the consultation when considering the derogations. Industry may not have access to comparable resources and thus the resulting essential use derogation process may lack the necessary data, increasing the possibility of uses being excluded from the Committee assessment. This is an impact of the redistribution of the burden and not specifically caused by the introduction of the essential use concept.

Clarity and predictability

By compiling various examples and opinions on the suitable criteria for essential use, we have estimated the outcome of the screening step 1.1 in this case study. As the criteria are not yet defined, these outcomes can only be estimates. **To correctly judge the essentiality of a use without the risk of speculative judgements a clear set of criteria is required. If clear criteria are provided this could offer stakeholders generally a higher level of predictability, especially in comparison with the current REACH restriction process**. The current approach of RAC and SEAC, although detailed and focused on certain aspects of the restriction, does not follow a process which is obvious to all stakeholders, the review of derogations and resulting opinions takes time and some complain this process is too long. By defining clear criteria and a clear process (such as Figure 7-4) industry would be more informed on the considerations and the decision-making process. As mentioned previously, concise guidance on the application of the criteria is key to avoid investing time in what will ultimately be unsuccessful derogations due to a lack of clarity.

Resulting derogations

Very few (1 out of 8 applicable derogations) of the derogations included in the most recent opinions from RAC and SEAC have been estimated to be granted based on the screening Step 1.1. However, this does not determine if the derogation would be granted after further technical or scientific assessment (Step 1.2). **Many of the derogations currently applied are not comparable to the essential use approach; they are used to refine the scope and focus the restriction on the concern raised in the dossier to mitigate unnecessary socio-economic impacts**. Additionally, the safe use derogations, 5a-c, are expected to remain and not include essentiality considerations, based on CARACAL discussions as of July 2022. The need for individual derogations specific to each essential use, for broad restrictions such as studied here, may negate any benefit from the streamlined stepwise process in comparison to the current approach in terms of efficiency, clarity and resource use. This approach would also increase the burden on industry as an increase in the number of derogations would be expected, leading to an increase in derogation seeking activity across industry. **These information requirements are predicted to considerably impact SMEs, because of resource limitations, and sectors not generally considered as essential because of complex information requirements.**

Summary of conclusions

The qualitative case study analysis suggests that **an essential use derogation could have resulted in a faster decision-making process specifically for the derogations considered for the restriction of intentionally added microplastics depending on multiple factors of the concepts implementation**. The considerations regarding sport field infill would have most likely been denied after Step 1.1 of the process based on the current understanding of the essential use concept. This derogation received a high-level discussion under the current approach, which could have been avoided under the essential use concept. However, by changing the approach of the derogations under the restriction process to focus on essential

uses, **there may be the requirement for an increase in the number of derogations to account for each use,** especially under broad restrictions such as studied here, which would extend the process. This is only one example of how the essential use derogation process may be applied, it is expected for the benefits and disadvantages to vary when applied to restrictions focused on single substances or with a narrow scope of application, further assessments of the application of the essential use derogation process would be valuable to fully comprehend the possible implications.

The **information burden** placed on the derogation applicant and the Committees, although different in scope, is **expected to be comparable** in the complexity and breadth of information required per derogation. Again, if the number of derogations were to increase to accommodate the need for individual derogations for each essential use, then the overall burden would also be expected to increase. **The information requirements placed on industry during a REACH restriction process would be expected to increase, as industry are expected to be responsible for the information requirements associated with derogations under the essential use derogation process.** Possibly impacting SMEs and sectors not deemed essential after assessment most significantly.

Finally, the **predictability and clarity of the process, if a stepwise approach is implemented and the criteria are defined clearly, could increase** and thus benefit all stakeholders if the criteria are clear. This conclusion is based on the current lack of obvious structure to the derogation assessment procedure carried out by RAC and SEAC. In particular this would allow industry to consider further in advance their investments in derogations or reformulation. This is **dependent on a clear communication of the essential use criteria**.

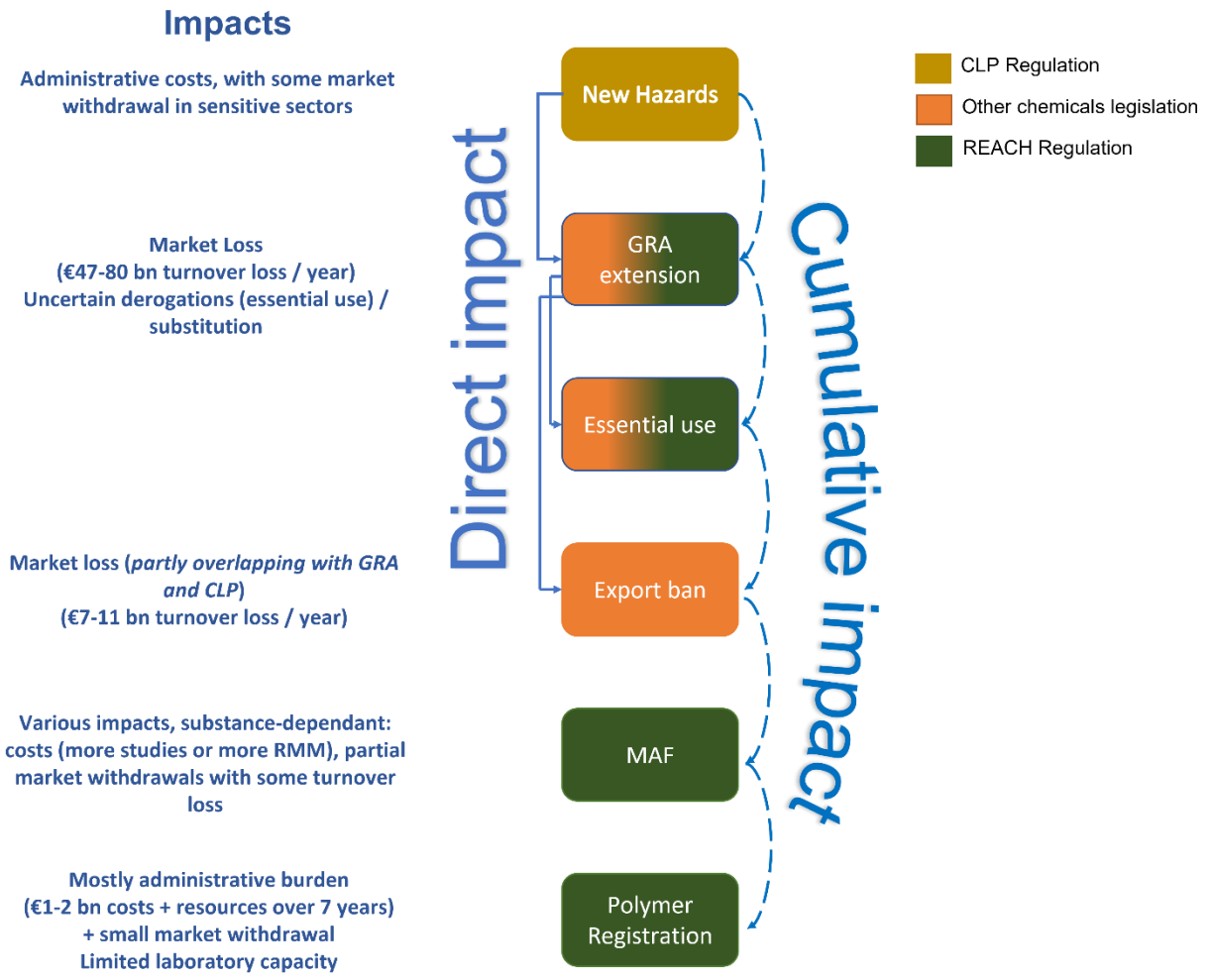
Should the essential use concept be applied for exemptions or derogations from the GRA, the complexity would be greater than for the example used in this analysis. This is due to the large number of substances that would be captured by the current and future GRA, and the broad, and sometimes multiple, uses. As such, Figure 7-4 would need to be applied to all substances subject to the GRA in the future, where a derogation is sought, once a harmonised classification has been granted.

8. OVERALL CONCLUSIONS

A targeted consultation with the chemicals industry and economic analysis has revealed that the changes proposed in the CSS and carried forward in this study are likely to have significant impacts on the EU chemicals sector and the wider economy. The actions that are assessed may be independent of each other (e.g. polymer registration) or directly linked to one another (e.g. additions of hazards to CLP and the extension of the GRA). Even where actions are independent of each other, there would be a cumulative impact for companies within the chemicals industry where they are required to implement more than one of the CSS actions. It has not been possible to assess the cumulative impact of all actions within the scope of this study, due in part to the large number of participants and the variation in products that each company places on the market, which in turn dictates the legal requirements with which they must comply. However, it is acknowledged that the cumulative impact of the CSS will be higher than the impacts presented here. There are a number of factors that shall contribute to the extent of the cumulative impact, for example:

- Although measures may be implemented over different timeframes, some will overlap, increasing the burden;
- The impact of the REACH restriction roadmap (which remains under development) or any further regulatory actions that may prohibit the placing on the market of chemicals. The time required for alternatives to be brought to the market varies by sub-sector and, in some cases, at product-level. Safety testing, risk assessment and product authorisation requirements increase the time to market. The faster the implementation of the CSS actions assessed in this Study, the higher the impact could be expected to be early on. With recovery rates unknown.

Figure 8-1 Overview of key impacts of selected CSS actions



8.1 CLP & GRA

The total potentially affected product portfolio from potential changes to the GRA and CLP represents approximately 43% of baseline turnover for the chemicals sector. When adjusted for uncertainties, the most likely affected portfolio is equivalent to 28% of the baseline turnover or market. When accounting for potential business responses, just these two policy changes could lead to a reduction in product portfolio/business (in turnover terms) of around 12% or equivalent to €70 billion of the 2019 market. This analysis reveals that EU chemical companies would lose between €47 billion to €81 billion of turnover per year on average between 2023 and 2040, when compared to baseline projections. The extent of this reduction will depend upon the scope and timetable of the legislative changes as well as the type of businesses responses expected. In 2040, in any of the policy scenarios considered in this study, sectoral turnover is estimated to be around €80 billion lower than in the baseline. The total contribution of the EU chemicals sector to GVA would be between €40 and €68 billion lower per year over this period, on average. It is also estimated that operating, capital and R&D expenditures would decline when compared to the baseline. These net reductions, however, would be driven by the significant losses that are estimated for the size or operations of the EU chemicals market. These estimates do not suggest that there will be any cost savings from the adoption of the legislative changes. In fact, unit expenditure is estimated to increase. The changes to GRA and CLP would also affect the sector's employment.

Over half of the chemical companies surveyed expect that the policy proposals will affect their competitiveness negatively or very negatively; less than 40% of respondents did not expect any significant impacts on their competitiveness; and around 5% reported expecting a positive impact. Illicit trade of restricted substances, mixtures and/or articles is a major concern among European chemicals companies, which is underpinned by the expectation that any reduction in the EU's supply of chemical products induced by policy changes would become a market opportunity for producers from outside of the EU.

There is also the need to consider the impact of these restrictions on consumers. By targeting such a large number of products, consumer choice is reduced. Although there is likely to be benefits to society from the increased protection of human health and the environment as a result of these policy changes, the lack of consumer choice in a digital age may also lead to more consumers purchasing products online from outside the EU, increasing the illicit trade in non-compliant products.

The impact on downstream users warrants further exploration. The analysis has shown that 60% of products in scope to be impacted by the addition of hazards to CLP and the extension of the GRA are professional products (74% professional and consumer products).

As a result of these policy changes, it could prove difficult for the EU to achieve its aim to "strengthen its open strategic autonomy with resilient value chains and diversify sustainable sourcing for those chemicals that have essential uses for our health and for achieving a climate-neutral and circular economy"[114].

The analysis of the potential impacts of a ban on exports reveals that EU chemical companies would experience annualised losses in turnover from exports that would range from €7 billion to €11 billion per year between 2023 and 2040, when compared to baseline projections. The extent of this reduction depends upon the scope and timetable of the legislative changes as well as the type of businesses responses expected. In 2040, sectoral turnover is estimated to be around €11.8 billion lower than in the baseline in all policy scenarios, albeit this is inherently uncertain and will depend on factors such as demand patterns, technological development, innovation and international competitiveness. There would be cumulative losses for companies which place products on the EU within scope of the GRA extension and on the export markets within scope of the export ban. Moreover, the majority (77%) of chemical companies surveyed for this study expect that manufacturers from outside of the EU-27 would increase their production to close any gaps in supply caused by a reduction in exports from the EU due to the proposed export ban.

The results of this assessment highlight that changes to CLP, the extension of the GRA, and the export ban, may lead to the reduction in manufacturing and/or use of chemical products currently on the market and the export of chemical products from the EU-27.

[114] Ibid footnote 12

8.2 MAF

Given the complexity of the application of MAF and the scope of this Study, a case study approach was selected to illustrate how a range of businesses, that is, REACH registrants, could be affected. As each substance is unique, it has not been possible to do a thorough quantitative assessment of the impact on all registered substances. The potential knock-on implications on the chemicals industry associated with the selected registrations and the broader economy were also characterised to the extent possible, more qualitatively. The quantitative and qualitative evidence on business and economic impacts for the two cases was employed to present the implications of a MAF of 10. Due to the consultation being limited to registrants of the substances (substance manufacturers or importers), supply chain effects have not been quantified in detail and may present a larger economic impact than is provided in this report.

Analysis revealed that the adoption of a MAF of 10 and the resulting business actions would have substantial impacts on their business activity and the associated supply chains due to the need to withdraw substances from the market and the introduction of stricter risk management measures which may reduce demand from customers further down the supply chain, due in part to the large investment needed. The impact of a MAF of 10 varies greatly depending on the substance properties and uses, i.e. high volume substances with multiple uses may be more likely to require significant adjustments and thus be more greatly impacted. In some cases, the generation of new data or refinement of exposure assessments can mitigate the implementation of a MAF, but in other cases it requires costly new control measures or withdrawal of substances from certain markets. These impacts would be exacerbated by the additional regulatory burden that the registrants would face and supply chains worth hundreds of billions would be affected and potentially disrupted, which would have additional negative economic implications across the EU.

8.3 POLYMER REGISTRATION

To assess the impacts of polymer registration a baseline and two policy scenarios were developed to assess the net impacts of this policy on the EU chemicals sector: the sectoral baseline, i.e., no polymer registration; two policy options (2019-2040) which assume that registration requirements will be introduced in 2025, with polymer manufacturers performing testing and submitting registration dossiers over a span of seven years. The two policy scenarios differ in their polymers grouping and testing strategies.

This analysis reveals that EU polymer manufacturing companies are estimated to experience an additional regulatory burden that would primarily apply in the first seven years from the introduction of REACH registration requirements for polymers. Over this short period, regulatory burden is estimated to increase from 0.4% in the baseline to up to 2.5% and 1.9% of turnover in Policy Option 1: REACH SIR and Policy Option 2: ECETOC central scenarios, respectively. That is the direct result of an additional annualised regulatory burden of €1.6 and €1.2 billion each year over the 7-year period 2025-2031, against the baseline. These significant increases in the regulatory burden faced by polymers manufacturers under Policy Option 1: REACH SIR– almost 6 times higher than the baseline's (no polymer registration) burden on average over the 7-year period over which costs are expected to be incurred, in the early years from adoption. Policy Option 2: ECETOC does also produce significant, albeit lower, increases in regulatory burden on aggregate, being around 4 times higher than the baseline's burden in the immediate seven years from adoption. This burden is subject to uncertainty in testing costs. This additional regulatory burden would lead to an increase in operating expenditures when compared to the baseline.

Impacts on the portfolio of products, business size and, thus, sectoral turnover from the introduction of REACH registration requirements for polymers are only expected in cases where companies are not able to absorb the additional regulatory burden, i.e., where increases in regulatory burden negatively affect the economic viability of certain products. As a result, in addition to increasing regulatory burden, the polymers sector in the EU-27 would be faced by turnover losses of 0.8% and 0.9% of the sector's turnover value under Policy Options 1 and 2 respectively, when compared against the baseline, and this result is driven by companies or product lines whose economic viability is affected by the regulatory costs. These reductions would be higher if companies are unable to absorb the additional regulatory burden, with more of their products becoming unviable from an economic perspective.

Based on these potential market losses against the baseline, it is estimated that the sector's direct contribution to GVA would be €1.1 and €0.9 billion lower per year between 2023 and 2040.

More than 90% of the polymer manufacturing and importing companies surveyed expect that the introduction of REACH polymer registration requirements will affect their competitiveness negatively or very negatively, and no company reported expecting a positive impact.

Regarding the testing activities required for registration, more than half of polymers companies surveyed for this study lack in-house laboratory facilities and, even the ones which do have such facilities consider that they would be unlikely to meet all of their testing needs due to limitations of testing capacity in the EU. Hence, there will likely be delays in the attainment of registration of all PRR in the sector once the polymers registration requirements are adopted.

The input collected from 11 CROs shows that testing capacity could be a rate-limiting factor. Capacity for testing varied greatly between CROs and tests. Although the sample of respondents does not represent the entire capacity of laboratories in Europe, it can be seen from the capacity reported that it may be difficult to have all PRR groups tested and registered within the first few years of implementation of polymer registration, particularly if the REACH SIR are taken forwards. Even with uncertainties, when grouping the polymers according to the two grouping strategies used in this study, there are likely to be more than 22,000 polymers requiring registration, which is close to the number of substances registered up until now (~23,000, including intermediates). For non-polymeric substances, a phased approach was used which may have helped to mitigate issues with laboratory capacity.

8.4 ESSENTIAL USE

This study focuses on the efficiency, clarity and regulatory outcomes of the essential use derogation approach, The costs or benefits to the protection of human health or the environment are not discussed or evaluated. This study has assumed a similar restriction process will be retained, but the derogations and transitional periods will include the concept of essential use. This is only one example of how the essential use derogation process may be applied, it is expected for the benefits and disadvantages to vary when applied to restrictions focused on single substances or with a narrow scope of application.

The qualitative analysis has predicted, based on the example of the REACH Restriction of intentionally added microplastics, that the stepwise application of the essential use concept to the derogation procedure could benefit the decision-making efficiency of 25% of the applicable derogations. The remaining 75% of the derogations were assessed to be inconclusive after the screening step and thus would require Step 1.2 which is expected to be comparable in volume of resource required to the current assessment by RAC and SEAC. These estimated decisions are based on clear essentiality (yet to be determined but estimated here) and clear alternatives available. As shown in the qualitative assessment, it can be expected for the screening of alternatives to be complex and therefore not benefit the efficiency of the process. Once essentiality is clearly defined by the Commission, a decision can be made on this aspect by the relevant committees depending on the relevance of the use, but this is unlikely to be the case with the screening of alternatives as most substance-use combinations are very specific and will require in-depth analysis.

The information requirements under the current process are cumbersome and have received criticism, however this is not expected to change with the implementation of the essential use concept. The information required for the derogation of uses which are considered essential may be reduced as life cycle emission considerations will not be a priority. A similar argument can be made regarding the Committee's considerations of uses that are clearly non-essential which will lead to rapid decision making and reduced burden. For uses with an ambiguous connection to human health/safety or the functioning of society the derogation proposal requirements and decision-making process could increase and become more complex leading to delays and increased burden. Additionally for broad restrictions there maybe the requirement for an increase in the number of derogations needed to cover multiple uses. This will impact industry significantly as it is expected for industry to provide a substantial volume of the derogation information. This redistribution of burden will alleviate the pressure on public authorities however this may hinder the accuracy of the process. These information requirements are also predicted to considerably impact SMEs, because of resource limitations, and sectors not generally considered as essential because of complex information requirements.

This qualitative assessment has focused on screening Step 1.1 of the proposed essential use derogation process. The resulting derogation decisions after further assessment have not be determined here as this would require in depth technical expertise and a defined concept of essential use. The final definition of essentiality will impact the efficiency and predictability of the essential use derogation process and determine

the benefits or drawbacks of this concept. The predictability and clarity of the process, if a stepwise approach is implemented and the criteria are defined clearly, is expected to increase and thus benefit all stakeholders if the criteria are clear. This conclusion is based on the current lack of obvious stricture to the derogation assessment procedure carried out by RAC and SEAC. In particular this would allow industry to consider further in advance their investments in derogations or reformulation.

8.5 KEY TAKEAWAYS

As a general conclusion, chemicals are crucial building blocks of all value chains – from everyday items to high tech products such as electronics, medical devices and car batteries. Securing domestic production of these building blocks is vital for the achievement of the European Green Deal and keeping strategic value chains here in the EU. This analysis has confirmed that the cumulative effect of only a handful of measures from the CSS will be significant and so the effect of all changes may be considerably higher. Furthermore, these impacts won't be limited to the chemical industry alone but affect a number of value chains relying on chemicals causing a so-called 'ripple effect' on value chains. To mitigate the impacts of each of these CSS actions, support would need to be provided to the chemicals industry through a clear implementation roadmap and the use of additional mechanisms be that financial, regulatory or additional time to respond to any policy changes, which could facilitate innovation and allow for new, more sustainable products to be brought to the market. The use of a phased approach to implementation, as was done for non-polymer substances previously could aid in mitigating economic burden but this would require further investigation.

Further analysis would be needed to assess whether the estimated costs to the EU-27 chemicals sector and the wider economy could be outweighed by any impacts of the proposed policy options on health, the environment and other economic impacts not considered in this study.

These conclusions are associated with the impacts on the EU chemicals industry as a result of the CS actions assessed in this study and any knock-on economic effects. By design, these conclusions do not provide any insights into the balance of economic, environmental and social impacts, nor the social costs and benefits of the proposed interventions.

T: +44 (0) 1235 75 3000
E: enquiry@ricardo.com
W: ee.ricardo.com