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Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability

Phase 1 Report

Report for the European Chemicals Industry Council (Cefic)

Final Report for European Chemicals Industry Council (Cefic)

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Contact:

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

T: +44 (0) 1235 753 104

E: becca.johansen@ricardo.com

Author:

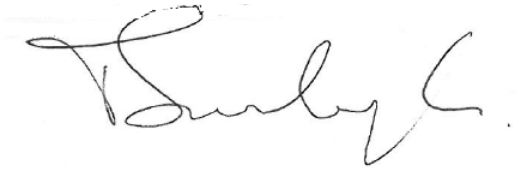
Becca Johansen, Brais Louro, Inge Kukla, Graham Pattle, Jodie Denmark, Chris Hughes (Ricardo)

Daniela Jeronimo Roque (Toxminds BvBA)

Approved by:

Tim Scarbrough

Signed



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Executive summary

Introduction

This study has been commissioned by the European Chemicals Industry Council (Cefic) to assess the business impacts to the European (EU) chemicals industry of selected actions from the EU Commission's (EC) Chemicals Strategy for Sustainability (CSS): Towards a Toxic-Free Environment[1]. This study shall feed into the Cefic response to the EU Commission's CSS Impact Assessments.

The European Union has one of the most comprehensive chemical regulatory frameworks in the world. This knowledge base helps to inform regulatory actions in other regions and has become a model for the safe use of chemicals[2]. The EU has been successful in maintaining the functioning of the single market, whilst reducing the risks to human health and the environment. This being said, studies[3,4,5] have noted the need to continue to improve current practices to ensure a higher level of protection.

The European Green Deal[6] was launched in December 2019 and sets out the European Commission's commitment to tackling environmental 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. 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*"[7].

The CSS was launched in October 2020, to provide a new long-term strategy for chemicals policy, in line with the aims of the EU Green Deal. 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 policy making in order to facilitate innovation of safe and sustainable chemicals, and the protection of human health and the environment.

Study Aims and Scope

This study seeks to assess the business impacts to the EU chemicals industry as a result of selected actions from the CSS. The study is composed of two phases:

Phase 1:

- Addition of hazards to the CLP Regulation (EC) No. 1272/2009[8];
- The extension of the Generic Risk Approach (GRA);
- The introduction of a Mixture Assessment Factor (MAF).

Phase 2:

- Requirements for Polymer Registration;

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[1] 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
[2] A. Bradford (2020) *The Brussels Effect: How the European Union Rules the World*. New York: Oxford University Press
[3] 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: evaluation-report.pdf (rpaltd.co.uk)
[4] Amec Foster Wheeler et al , 2017. Study supporting the Fitness Check on the most relevant chemicals legislation ("Fitness Check +")
[5] 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
[6] 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
[7] Ibid footnote 6
[8] *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

- The implementation of the PFAS ban;
- The application of an export ban; and
- Extending REACH Registration requirements to chemicals produced in low tonnage bands.

The work has followed the EU Commission's Better Regulation Guidelines[9] where possible, although as this is an analysis of business impacts only, **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.

This report presents the findings of an analysis of the business impacts of:

- The addition of hazards to the CLP Regulation
- The extension of the Generic Risk Approach (GRA).

This study ran from February to October 2021. The scope of this study is related to business impacts such as compliance and operating costs, as well as manufacturing and use restrictions, 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 (removal from the market, substitution, reformulation).

Policy 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 a key role 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 planet as a whole, potentially contributing to global crises such as climate change, biodiversity loss and environmental degradation.[10]

The EU has regulated the exposure of humans and the environment to hazardous substances for over 50 years, with the original Community legislation relating to classification of substances being adopted in 1967 (the Dangerous Substances Directive - 67/548/EEC) and extended to preparations (now termed mixtures) in 1988 (88/379/EEC). Chemicals policy has changed over the last half century from being reactive to evidenced risks to proactively identifying hazards and potential risk, and mitigating this.

The EU chemicals acquis has evolved, with many pieces of legislation being developed in parallel to those outlined above. The comprehensive EU chemicals legislative framework now comprises around 40 pieces of legislation, including but not limited to: Regulation (EU) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[11]; and Regulation (EC) No. 1272/2009 on the Classification, Labelling and Packaging of hazardous substances (CLP)[12].

As the overarching pieces of chemicals legislation, the REACH Regulation and CLP Regulation introduced different regulatory management measures for substances, mixtures and, in the case of REACH, articles, which display a range of hazardous properties, with more restrictive risk management for those which are deemed to be of highest concern. Despite the increased regulatory

[9] European Commission (2017) *Better regulation: guidelines and toolbox.* Available from: Better regulation: guidelines and toolbox | European Commission (europa.eu)
[10] Ibid footnote 1
[11] *Regulation (EC) No 1907/2006 of the European Parliament and of the Council 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
[12] Ibid footnote 8

management of hazardous substances, recent regulatory reviews have noted that more needs to be done in order to ensure a high level of protection to human health and the environment[13,14,15,16,17].

Context: 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).[18]

Context: Risk Assessment has followed two main approaches in the EU

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) [19]. 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 publication of the CSS included use of the terminology '*generic approach to risk management'*, hereby referred to as GRA, and the SRA, which were defined as follows:

> *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).* [20]
>
> *'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'*[21]

The GRA is utilised by a number of pieces of EU chemicals legislation and is seen as reflective of the 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.

EU chemicals legislation incorporates the specific risk approach in two main ways: [22]

- **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

[13] European Commission (2018) *Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee: Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions.* SWD(2018) 58 final. COM(2018) 116 final. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN
[14] Ibid footnote 3
[15] Ibid footnote 4
[16] Ibid footnote 5
[17] 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
[18] UK Health and Safety Executive. (n.d.) *Background: Globally Harmonized System (GHS)*. Available from: https://www.hse.gov.uk/chemical-classification/legal/background-directives-ghs.htm
[19] 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)
[20] Ibid footnote 1
[21] Ibid footnote 1
[22] Ibid footnote 4

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.

The approach follows the Commission's Better Regulation Guidelines, where possible

The European Commission's Better Regulation Guidelines and Toolbox[23] 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 European 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.

In this context, the assessment has been developed, to the extent possible, in accordance with the European Commission'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.

These 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 European Commission's Better Regulation Guidelines, and particularly drawing from Tool #14 and Tool #17.
- **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 of measures was screened to identify which are likely to be most impactful, following an approach inspired by Tools #57 and #63 of the Better Regulation Guidelines. This process resulted in a selection of the most impactful policy options for consideration, including, for example, proposed changes to the Generic Risk Approach (GRA) and the addition of new hazards to the EU's Classification, Labelling and Packaging (CLP) Regulation. In order 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 #19 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. These are operating costs and conduct of business, administrative burden on businesses, position of SMEs, innovation and research, and the macroeconomic environment. Across these impact categories, different types of economic costs and benefits were considered based on Tools #58-60 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, which is focussed on the Chemicals industry and industry-driven economic effects.

[23] Ibid footnote 9

- **Step 4: Stakeholder consultation and evidence gathering.** Stakeholder engagement was a horizontal task, central to this study and feeding into all of the aforementioned steps. The consultation activities and data analysis carried out in this Study were based on Tool #54 (and others) of the Better Regulation Toolbox, as pertinent. These activities included two targeted consultations with business stakeholders. In addition, the consultation activities were complemented by a rapid literature review.

  Due to the nature of this project, the consultation activities were not open to the wider public and targeted chemical companies that are Cefic members and members of partner associations[24]. This was deemed appropriate for the purposes of this study as it focusses on assessing business impacts and participants from Cefic[25] and partner associations represent the majority of the EU chemicals sector. The sample, in numbers, is statistically representative, with a margin of error +/- 10% (Section 2.5)

  Data collection and consultation were conducted in strict compliance with competition law, ensuring confidentiality of individual company submissions and sufficient aggregation of results prior to release. Two key targeted stakeholder consultation exercises were central to the study. The consultations covered:

  - The identification of substances to be regulated under GRA and CLP and product portfolio scoping
  - The consideration of business and economic impacts of changes to the GRA and CLP.

- **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 #59-62 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 through a business survey; and statistical techniques for the extrapolation of impacts from the survey sample to the EU-27 chemicals sector.
- **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.

Table 1-1 presents the limitations of the methodology and the implications these have had on the analysis.

Table 1-1 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	An estimate of how grouping may expediate regulatory action has been included in the weighting of hazard classifications. This is based on limited evidence and the grouping of

[24] Participation was open to companies from national chemical federations and downstream user federations.
[25] Cefic, (2021). *Membership*. [Online] Cefic. Available from: https://cefic.org/about-us/membership/

Limitations	Implications
and how this would interact with the impacts of legislation. • How grouping of chemicals will affect the speed of regulation	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 (84 large vs 17 SME), while they are a minority in the sector (800 out of 28 thousand)[26]. However, the sample covers two-thirds of the sector's turnover, thus being 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).

Policy options brought forward for assessment

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 1-2. Assumptions have been developed by the study team and Cefic and are based on literature review of publicly available information.

Changes to the CLP

New hazard classes (ED, PBT, vPvB, PMT, vPvM, Immnunotoxicants 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.

The inclusion of new hazard classes in CLP will not result in an immediate reharmonization 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

[26] 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.

generated evidence necessary to support classification, as well as resource availability from authorities.

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, etc.). 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.

Changes to the GRA

According to the CSS Communication, the Generic Risk Approach 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, it is employed via REACH Restriction (including Article 68(2)) and sector specific legislation.

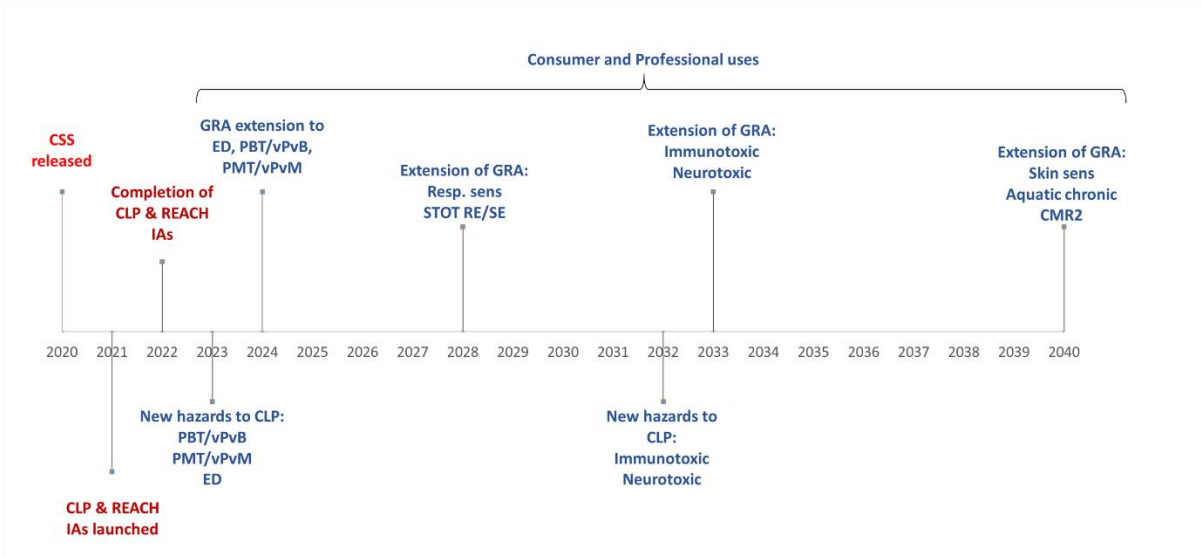
Table 1-2 Shortlist of policy options and assumptions used in the analysis

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	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 define the modalities and timing for extending the same generic approach, with regard to consumer products, to further harmful chemicals, including those affecting the	Extend the generic risk approach to consumer and professional uses via REACH Restriction (e.g. Article 68(2)) and sector specific legislation: • ED • PBT/vPvB • PMT/vPvM	2024
		Extend the generic risk approach to consumer and professional uses via REACH Restriction (e.g. Article	2028

	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	68(2)) and sector specific legislation: • Resp sens. Cat. 1, 1A & 1B • STOT RE/SE Cat. 1 & 2	
		Extend the generic risk approach to consumer and professional uses via REACH Restriction (e.g. Article 68(2)) and sector specific legislation: • 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 1-1 below presents the indicative policy timeline that has been assumed in our assessment of the impacts.

Figure 1-1 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 (SVHC> resp. sens./ STOT RE/SE) 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.

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

Table 1-3 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

Conclusions

The EU-27 chemicals 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 on the EU-27 market worth over €570 billion per year[27], 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)).

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.

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 a series of assumptions 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);

[27] This figure represents the sales of products manufactured in the EU-27 sold in the EU-27 or abroad, and any other products placed on the EU-27 market. All monetary figures are expressed in 2020 constant euros.

- 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) and in the absence of further clarification from the Commission. 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).

European Commission's definition of SoC

"*…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*"[28]

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[29] (F1/F2) are in place. 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 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 (2021).

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.

[28] 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
[29] CMR 1A/1B, PMT, vPvM, PBT, vPvB, ED, STOT SE/RE 1/2, Respiratory Sensitisers, Immunotox, Neurotox.

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 would 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.

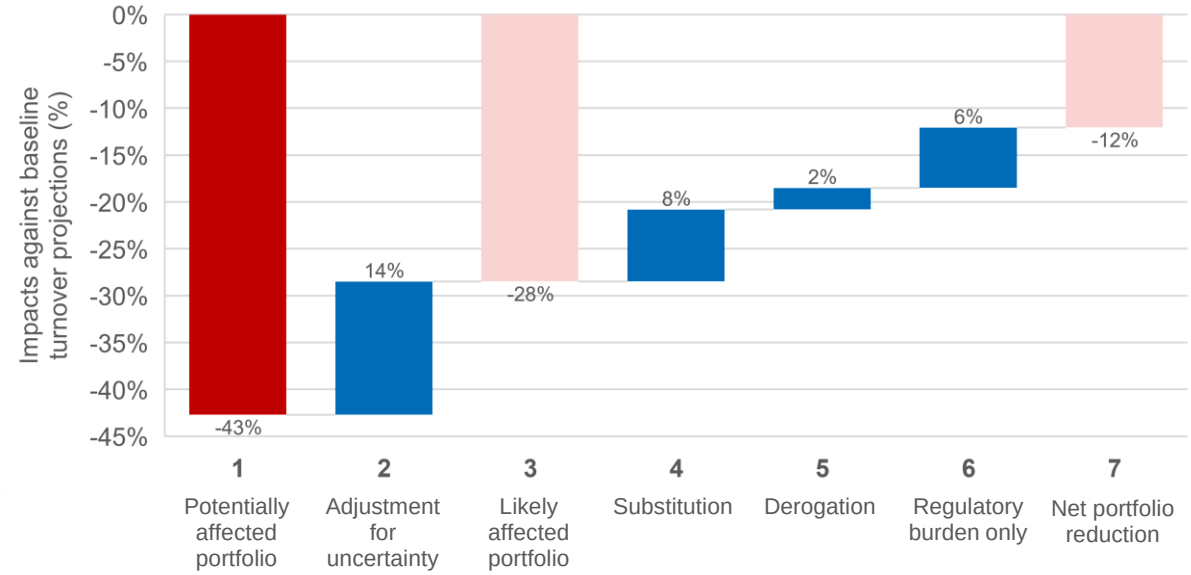
In addition, a quarter of the products that may only be affected by changes to CLP are expected to face indirect pressures to withdraw their products from the market. These businesses would also be able to substitute and/or reformulate some of their products to mitigate any potential market losses.

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.

Finally, Figure 1-2 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).

Figure 1-2 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**).

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[30]. This baseline scenario assumes that CSS is not implemented, GRA is not extended, and CLP remains unchanged.
- A first policy scenario (**Scenario 1**) considers the addition of hazard classes to CLP and extension of the GRA over a gradual implementation timetable, as outlined in Table 1-2 (or Figure 1-1). 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.
- A second scenario (**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 of 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.
- A third scenario (**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[31], 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.

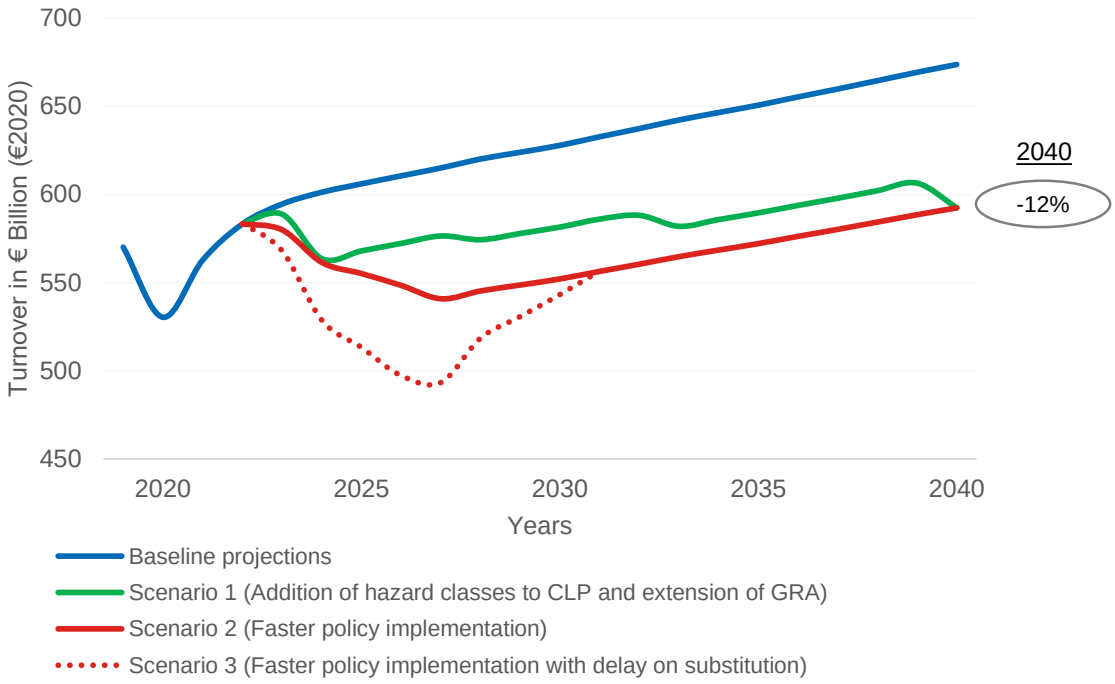
The net impacts on the EU-27 chemicals sector and the knock-on effects on the EU-27 economy in each of these policy scenarios were analysed against the baseline.

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 the Figure below. 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.

[30] Eurostat (2021), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 09/2021]

[31] 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

Figure 1-3 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.**

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 1-4 Annualised impacts on selected business and economic indicators of the EU chemicals sector, against the baseline scenario (%)

Themes (business or economic indicators)	**Scenario 1** (Addition of hazard classes to CLP and extension of the GRA)	**Scenario 2** (Faster, 5-year implementation timetable)	**Scenario 3** (Faster implementation timetable with delay on substitution/ reformulation)
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 **74% of products in scope** to be impacted by the addition of hazards to CLP and the extension of the GRA are **professional or consumer products**. 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 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"[32].

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.

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.

[32] Ibid footnote 28

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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
PP	Percentage point
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 Background to the Study

This study has been commissioned by the European Chemicals Industry Council (Cefic) to assess the business impacts to the European (EU) chemicals industry of selected actions from the EU Commission's (EC) Chemicals Strategy for Sustainability (CSS): Towards a Toxic-Free Environment[33]. This study shall feed into the Cefic response to the EU Commission's CSS Impact Assessments.

The European Green Deal set out a new growth strategy for Europe to become a sustainable, climate neutral and circular economy by 2050 and to better protect human health and the environment by moving towards a toxic-free environment.

Chemicals play a fundamental role in the functioning of our daily lives. They protect our health, contribute to food security, and are the building blocks of the products that we rely on every day. As chemicals have wide dispersive uses and play such a key role 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 planet as a whole, potentially contributing to global crises such as climate change, biodiversity loss and environmental degradation.[34]

The European Union has one of the most comprehensive chemical regulatory frameworks in the world. This knowledge base helps to inform regulatory actions in other regions and has become a model for the safe use of chemicals[35]. The EU has been successful in maintaining the functioning of the single market, whilst reducing the risks to human health and the environment. This being said, studies[36,37,38] have noted the need to continue to improve current practices to ensure a higher level of protection. As such, the EU Chemicals Strategy for Sustainability was launched in October 2020, to provide a new long-term strategy for chemicals policy, in line with the aims of the EU Green Deal. The CSS strives for a toxic-free environment, where chemicals are manufactured and used in a way that can maximise their societal contribution but avoid 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 policy making in order to facilitate innovation of safe and sustainable chemicals, and the protection of human health and the environment.

1.2 Study Aims and Scope

This study seeks to assess the business impacts to the EU chemicals industry as a result of selected actions from the CSS. The study is composed of two phases:

Phase 1:

- Addition of hazards to the CLP Regulation (EC) No. 1272/2009[39];
- The extension of the Generic Risk Approach (GRA);

[33] 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
[34] Ibid footnote 33
[35] A. Bradford (2020) *The Brussels Effect: How the European Union Rules the World*. New York: Oxford University Press
[36] 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: evaluation-report.pdf (rpaltd.co.uk)
[37] Amec Foster Wheeler et al, (2017). *Study supporting the Fitness Check on the most relevant chemicals legislation ("Fitness Check +")*
[38] 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
[39] *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

- The introduction of a Mixture Assessment Factor (MAF).

Phase 2:

- Requirements for Polymer Registration;
- The implementation of the PFAS ban;
- The application of an export ban; and
- Extending REACH Registration requirements to chemicals produced in low tonnage bands.

The work has followed the EU Commission's Better Regulation Guidelines[40] where possible, although as this is an analysis of business impacts only, **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.

This report presents the findings of an analysis of the business impacts of:

- The addition of hazards to the CLP Regulation (EC) No. 1272/2009[41]
- The extension of the Generic Risk Approach (GRA).

This study ran from February to October 2021. 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 (removal from the market, substitution, reformulation).

1.3 Report Structure

This report is structured in the following sections:

- Section 1: Introduction
- Section 2: Methodology – ex ante Assessment of Business Impacts
- Section 3: Context and Baseline Scenario
- Section 4: Current Legislative Approach
- Section 5: Policy Options Considered
- Section 6: Policy and Legal Implications
- Section 7: Business Impacts of Policy Options
- Section 8: Conclusions

[40] European Commission (2017) *Better regulation: guidelines and toolbox.* Available from: Better regulation: guidelines and toolbox | European Commission (europa.eu)
[41] Ibid footnote 39

2 Methodology: ex ante Assessment of Business Impacts

This section provides an overview of the methodology used to perform an ex ante assessment of the business impacts to the EU chemicals industry and associated economic effects as a result of the selected policy options from the CSS (section 2.1). Following this, the approach taken to develop the baseline against which the impacts were assessed is described (section 2.2) and the processes for specifying the policy options (section 2.3) and mapping and screening impact categories (section 2.4) are outlined. The evidence gathering process, an essential step in this project, is summarised (section 2.5), as well as the methods employed to assess impacts (section 2.6). A brief presentation of limitations and quality assurance approaches are also presented (section 2.7).

2.1 Overview

The European Commission's Better Regulation Guidelines and Toolbox[42] 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 European level ahead of implementing a policy action.

This ex-ante assessment of selected policy options that are already proposed within the CSS is focussed 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.

In this context, the assessment has been developed, to the extent possible, in accordance with the European Commission'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.

These 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 European Commission's Better Regulation Guidelines, and particularly drawing from Tool #14 and Tool #17.
- **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 of measures was screened to identify which are likely to be most impactful, following an approach inspired by Tools #57 and #63 of the Better Regulation Guidelines. This process resulted in a selection of the most impactful policy options for consideration, including, for example, proposed changes to the Generic Risk Approach (GRA) and the addition of new hazards to the EU's Classification, Labelling and Packaging (CLP) Regulation. In order 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 #19 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 Tools #58-60 of the Better Regulation Toolbox. Social and environmental impacts and, therefore,

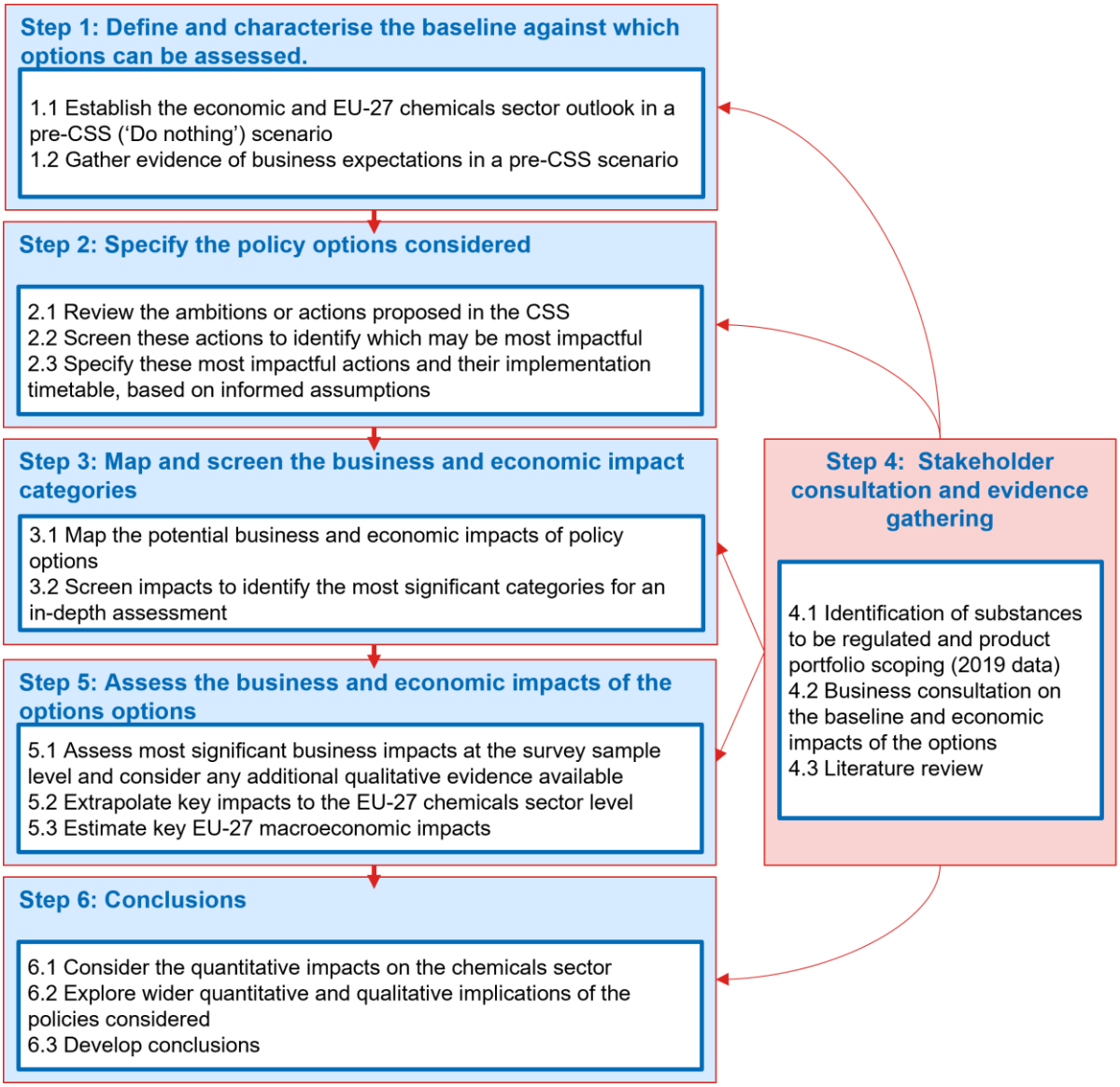
[42] Ibid footnote 40

any indirect economic impacts driven by these, were not in scope of this exercise, which is focussed on the Chemicals industry and industry-driven economic effects.

- **Step 4: Stakeholder consultation and evidence gathering.** Stakeholder engagement was a horizontal task, central to this study and feeding into all of the aforementioned steps. The consultation activities and data analysis carried out in this Study were based on Tool #54 (and others) of the Better Regulation Toolbox, as pertinent. These activities included two targeted consultations with business stakeholders. 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 #59-62 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 through a business survey; and statistical techniques for the extrapolation of impacts from the survey sample to the EU-27 chemicals sector.
- **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 below.

Figure 2-1 Overview of the core methodological steps underpinning this ex-ante assessment of business and economic impacts[43]



The following sections describe the methods employed in steps one to five in more detail. The core limitations identified and the quality assurance approaches employed are also described.

2.2 Define and characterise the baseline

This study defined and characterised how the EU Chemicals sector would likely evolve without any further policy changes in EU Chemicals legislation, drawing from Tool #14 and Tool #17 of the EC's Better Regulation Toolbox. This includes:

[43] 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.

- Defining the 'Do nothing' **policy scenario**, that is, what EU Chemicals legislation would look like in the absence of the CSS;
- Identifying key economic and sectoral indicators that can be used to characterise the potential evolution of the **EU Chemicals sector;** and
- Quantifying how these indicators may evolve over a period of 20 years (2020-2040).

First, policy experts from the study team defined what the 'Do nothing' scenario would look like in terms of EU Chemicals legislation. In particular, study team experts reviewed the existing legislation and expected changes already agreed and implemented in the legislation over the timeline. These assumptions were most useful to establish the additional requirements that may result from the implementation of the CSS. In general, from a business perspective, it was assumed that the existing framework would continue broadly as-is over the period with periodical harmonised classification and labelling (CLH) updates to the CLP Regulation and subsequent poison centre notification (PCN) updates.

Secondly, the team established a set of proxy indicators of focus to characterise the baseline of the EU Chemicals sector and the EU-27 economy, which would become the core indicators and baseline against which the policy options would be assessed. Based on their relevance and the evidence available from Cefic and Eurostat, Table 2-1 below outlines the selected indicators. This excludes specific indicators that would capture international trade, as the specific effects on exports and competitiveness were not addressed in detail as part of this study.

Table 2-1 Sectoral indicators selected for the baseline characterisation[44]

Theme	Indicators
GDP and growth	• Sectoral output or production value or turnover (€ billions) • Sectoral Gross Value Added (€ billions), approximately capturing the sector's contribution to Gross Domestic Product) • Gross investment (€ billions) • Operating expenditure (€ billions) • Research and Development expenditure (€ billions)
Regulatory burden	• One-off or recurring regulatory costs (€ billions)
Employment	• Number of jobs supported by the sector (Number of jobs)

Thirdly, historical evidence was collated from Eurostat and Cefic across each of these indicators for a 10-year period (2008 – 2019). Analytical techniques, such as econometric modelling, were employed to extrapolate, based on this evidence in a 'Do nothing' scenario, how each indicator may develop over the next 20 years (2020 – 2040). This exercise provides a quantitative scenario or illustration of how the sector could develop in the absence of further legislative action, any transformative international developments that may significantly affect the European market, and/or unknown exogenous shocks, among others.

Both the qualitative and quantitative baselines developed as part of this exercise, further described in Section 3, serve as counterfactuals against which the effects of the policy options have been assessed in this study.

[44] International trade and competitiveness were not quantitatively assessed due to the study's scope and limited availability of evidence and, therefore, a detailed baseline characterisation was not carried out at this stage.

2.3 Specify the policy options considered

The CSS was reviewed to produce a longlist of (80+) measures or action points that the EC could take forward. This study does not attempt to assess the impacts of all of these measures, rather focus on the measures that may be most impactful from the EU Chemicals sector's perspective.

This longlist of measures was, therefore, screened to identify which measures or action points are likely to be most impactful, following an approach inspired by Tools #57 and #63 of the Better Regulation Guidelines.

Five criteria were developed against which each of the measures or action points were assessed or scored, between 1 (Low score or negative impact) and 5 (High score or a negative impact). These are:

- Overall effectiveness (covering the likelihood that a measure could achieve intended policy objectives)
- Overall efficiency (considering the potential balance of costs and benefits for each measure)
- Overall proportionality (assessing the extent to which a measure could be prohibitive or render certain activities no longer possible due to the additional burden and/or restrictions introduced)
- Direction of impact on businesses (analysing whether business would be positively or negatively affected by measures overall)
- Scale of impact on businesses (assessing the potential magnitude of the impacts on businesses)

This screening process resulted in a selection of the most impactful policy options for consideration, that is, the shortlist of policy options. This shortlist was further concretised so that selected policy options could be assessed in more depth, for example, the extension to the GRA and addition of hazards to CLP. To do so, policy experts:

- Reviewed the CSS and identified key commitments in detail
- Translated these commitments into concrete policy assumptions
- Employed these informed assumptions to develop concrete policy options and their associated implementation timelines
- Tested these outputs with pertinent stakeholders
- Established final policy options for consideration in this study.

An illustration of the shortlist is presented in Table 2-2 and more detailed outputs of this process are also described in Section 0.

Table 2-2 Shortlist of policy options

Commitment or ambition	Action	Concrete Policy Option
Stronger EU legal framework to address pressing environmental and health concerns	1. Extension of the Generic Risk Approach	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 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) Define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments. 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) Introduce endocrine disruptors (ED), persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances as categories of substances of very high concern (SVHC)
	2. 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
	3. Mixture Assessment Factor	a) Assess how to best introduce in REACH (a) mixture assessment factor(s) (MAF) for the chemical safety assessment of substances
Simplifying and consolidating the legal framework	4. Addition of Hazards to CLP	a) Ensure that the CLP Regulation is the central piece for hazard classification and allows the Commission to initiate harmonised classifications
A comprehensive knowledge base on chemicals	5. Polymer Registration	a) Make a proposal to extend the duty of registration under REACH to certain polymers of concern
	6. Increased Information Requirements	a) Amend REACH information requirements to enable identification of all carcinogenic substances manufactured or imported in the EU, irrespective of the volume

2.4 Map and screen the business and economic impact categories

First, a longlist of twelve (primarily) economic impact categories was developed and screened, using the language employed and structure from Tool #19 of the Better Regulation Toolbox. This excluded any non-economic impact categories as the focus for this study was on analysing how the EU-27 chemicals sector may be affected and any potential knock-on effects on the EU-27 economy.

Table 2-3 Longlist of the impact categories mapped for screening

Impact category	Impact Sub-categories
Economic	• Operating costs and conduct of business (e.g. substantive compliance costs) • Administrative burdens on businesses (e.g. costs associated with notification obligations or other administrative activities) • Trade and investment flows (e.g. imports or exports effects) • Competitiveness (sectoral) of businesses (e.g. effects on the market share and comparative advantages in an international context) • Position of SMEs (e.g. burden on small firms and impacts on their financial sustainability, etc.) • Functioning of the internal market and competition (e.g. impacts on the free movement of goods) • Innovation and research (e.g. stimulation or hindrance of investment in chemical alternatives, etc.) • Public authorities (e.g. administrative costs from additional requirements, etc.) • Consumers and households (e.g. ability to benefit from the internal market) • Third countries and international (e.g. effects on EU foreign policy) • Macroeconomic environment (e.g. consequences on economic growth and employment)
Social	• Employment (e.g. number of jobs created or lost)

This mapping is based upon the development of impact pathways for each of the policy options considered. The pathways highlighted how pertinent stakeholders may be affected: enterprises (Chemical manufacturers and formulators or NACE[45] #20), workers, consumers, EU citizens, public authorities and third countries. Further, across each of these impact categories, different types of economic costs and benefits were considered based on Tool #58-60 of the Better Regulation Toolbox.

Following this mapping, a screening exercise was conducted to identify the most significant impact categories for a more in-depth assessment. This exercise focussed on the categories of most relevance or impact on chemical manufacturers (enterprises), and considered the following:

- The magnitude of the potential impact and whether the impact is more or less significant for certain business stakeholders (i.e. SMEs versus large firms)
- The likelihood or uncertainty of an impact materialising

[45] 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)

- The relation to the underlying initiative (i.e. whether it is a direct and/or indirect impact of the actions considered for Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[46] or CLP under the CSS)
- The relevance of the impact in meeting the EU's ambitions or commitments (i.e. whether the impact is aligned or not with the underlying objectives for amending the Regulation)
- The importance of impacts in meeting any other EU objectives and policies.

This screening exercise was based on evidence collected through secondary research and rapid literature review of published reports and papers, input from Cefic members gathered through consultation activities, and the knowledge and expertise of the project team.

As a result, five sub-categories of impact were identified as likely to be significant for a more in-depth quantitative assessment. Two additional sub-categories were considered for qualitative exploration and, where possible, quantitative assessment, depending on the evidence available and their relevance for the key business impacts of the policy options considered. Table 2-4 outlines this shortlist of impacts mapped against the indicators selected for assessment as outlined in the earlier baseline section.

Table 2-4 Shortlist of the economic impacts for more in-depth assessment, and how these are linked to the indicators selected for the quantitative assessment

Priority	Key Impact sub-categories	Indicators selected as proxies for these key impact sub-categories
Primary impacts	• Operating costs and conduct of business (e.g. substantive compliance costs) • Administrative burdens on businesses (e.g. costs associated with notification obligations or other administrative activities) • Position of SMEs (e.g. burden on small firms and impacts on their financial sustainability, etc.) • Innovation and research (e.g. stimulation or hindrance of investment in chemical alternatives, etc.) • Macroeconomic environment (e.g. consequences on economic growth and employment) Employment (e.g. number of jobs created or lost)	• Sectoral output or production value or turnover (€ billions), where possible by business size (**Turnover**) • Sectoral Gross Value Added (€ billions), approximately capturing the sector's contribution to Gross Domestic Product) (**GVA**) • Gross investment (€ billions) (**CAPEX**) • Operating expenditure (€ billions) (**OPEX**) • Research and Development expenditure (€ billions) (**R&D**) • One-off or recurring regulatory costs (€ billions), where possible by business size (**Regulatory burden**) • Number of jobs supported by the sector (Number of jobs) (**Employment**)
Secondary impacts	• Trade and investment flows (e.g. imports or exports effects) • Competitiveness (sectoral) of businesses (e.g. effects on the market share and comparative advantages in an international context)	These sub-categories were considered qualitatively and captured indirectly as part of the analysis of turnover and GVA (since exports contribute to the sectoral turnover and GVA in the EU).

[46] *Regulation (EC) No 1907/2006 of the European Parliament and of the Council 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

Although these categories are likely to be most significant for both the GRA and CLP changes, the specific impacts across these categories would differ in nature, direction, and scale.

Finally, any social and environmental impacts of these policy measures and, therefore, the associated indirect economic impacts driven by these (e.g. health effects and how those may impact on productivity or the public and private health systems across the EU), were not in the scope of this exercise, which focusses on the Chemicals industry and industry-driven economic effects.

2.5 Stakeholder consultation and evidence gathering

The evidence requirements for this assessment of business impacts are vast. There are a large number of product sectors that can be categorised into base chemicals, specialty chemicals and consumer chemicals. There is also a wide variation in how the EU chemicals legislation is implemented across these sectors. Further, the evidence available in published reports and studies, as well as economic data of the EU Chemicals sector already published by Cefic and Eurostat, would be insufficient to quantify potential business impacts of the policy options considered without the introduction of a wide range of assumptions. Therefore, engaging business stakeholders to gather primary evidence on their operations and potential effects of changes to GRA and CLP was central to this assessment.

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 with business stakeholders. In addition, the consultation activities were complemented by a rapid literature review. Due to the nature of this project, the consultation activities were not open to the wider public and targeted at Cefic and partner associations members only. This was deemed appropriate for the purposes of this study as it focusses on assessing business impacts and Cefic has 670 business members and affiliates[47] that represent the majority of the EU Chemicals sector in terms of sales and output.

Two key targeted stakeholder consultation exercises were central to the study. The consultations covered:

- The identification of substances to be regulated and product portfolio scoping
- The consideration of business and economic impacts of changes to the GRA and CLP.

The EU Chemicals sector includes more than 28,000 companies[48]. Across these two activities, the ambition of the project has been to engage with a representative sample of businesses, within the limitations of time and resources. These consultation exercises engaged more than 100 business respondents that represent a significant proportion of the EU-27 chemicals sector output (67%)[49]. This sample would, therefore, broadly represent the sector's mean with a 95% confidence interval and a margin of error of around +/- 10%. More details are provided in Annex 4.

The sample does, however, comprise a disproportionate number of large firms. This is not deemed a significant issue for this assessment, especially since the majority of sectoral output is captured by the sample. Nevertheless, 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[50].

The two engagement activities are considered in more detail in the following sections.

[47] Cefic, (2021). *Membership*. [Online] Cefic. Available from: https://cefic.org/about-us/membership/
[48] Eurostat (2021), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 09/2021] and Cefic (2018). *Facts and Figures*. Available from: https://www.apquimica.pt/uploads/fotos_artigos/files/cefic-facts-and-figures-2018-industrial.pdf
[49] 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. 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.
[50] The sample of SME respondents has a size of 17, which implies that any estimates for this group should be taken as indicative only.

2.5.1 Identification of substances to be regulated and product portfolio scoping

Firstly, a technical consultation of business stakeholders was carried out to identify and quantify the size of the **portfolio of products that may be affected** by the changes to the GRA and CLP. In order to do this, a list of current and potential future substances to be regulated, hereafter "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 based on a series of assumptions 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 and 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). 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).

European Commission's definition of SoC

"*…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]

The aim of this exercise was to quantify, based on the policy options considered and their assumptions, which products may be regulated as a result of the extension of the GRA and the addition of hazards to CLP due to their containing one or more substances present on the "List of Substances to be Regulated" at a concentration greater than the generic concentration limit (GCL) for mixture classification. For new hazard endpoints, a GCL of 0.1% was used. Data obtained in this exercise was used in combination with data from the second consultation, outlined in section 2.5.2, to assess the extent to which they might be affected.

Data of the products that may be potentially affected, in any way, by the concrete policy options considered in this study, were collected across the following dimensions from more than 100 businesses:

- Volume of products manufactured in the EU-27 (€ and tonnes - in range) by product
- Volume of products imported and placed in the EU-27 market without any significant adjustments (€ and tonnes – in range) by product
- Volume of products manufactured in the EU-27 (€ and tonnes – in range) targeting a market outside of the EU-27 (i.e. for export outside of the EU-27) by product

[51] Ibid footnote 33

- Type of product: Substance, mixture, article, UVCB
- Use type/ end use: industrial, professional, consumer
- Product sector: sectors where these products sold for their end use e.g. PC8 Biocidal products[52]
- Percentage of total sales per sector
- Applicable hazard classification

Over 100 businesses responded to this consultation. The outputs provide us with an estimate of the size of the affected portfolio of products (both in volume and in sales) in the EU Chemicals sector that offers a basis for considering direct and indirect impacts on the sector's operations and contribution of the EU economy.

This consultation also offers further information that can be used to consider the potential distribution of impacts across sectors in the EU, among others.

2.5.2 Design and implementation of an economic impact survey

Secondly, an economic impact survey, targeting the same sample of businesses engaged in the previous consultation, was implemented. The aim of this survey was to collect evidence that would form the basis for an assessment of the **extent to which the portfolio of chemicals products in the EU-27 would be indeed affected,** once businesses respond to the legislative changes e.g. through substitution, reformulation and/or applications for derogation[53]; and quantify key knock-on effects based on evidence collected from businesses directly, as much as possible.

A four-part, 70-question survey was designed to elicit evidence and informed views from businesses:

- Part 1, gathering data about the respondents, in terms of their size, activities, main country of operation, etc.
- Part 2, seeking to form a baseline, including of their turnover, investment, expenditures, employment, regulatory burden and other key proxies of their economic activity.
- Part 3, considering direct business responses and associated costs and benefits (e.g. substitution, reformulation and/or derogations; investments; expenditures; and employment) over at least 10 years from adoption of changes to the GRA and CLP.
- Part 4, collecting information on other economic impacts, primarily qualitative (e.g. imports/exports and competitiveness).

The survey covered all of the key business and economic impacts that were screened as potentially most significant (Section 2.4). The types of questions covered across these key business impacts and/or proxies for these impacts are outlined in Table 2-5.

Table 2-5 Types of questions covered by the economic impact survey

Policy, key business impacts or proxies	Information sought by the survey for evidence on operations in the EU-27 (not an exhaustive list)
Policy	• Establishing the relevance of certain policies and/or legislation for each respondent and their suppliers
Turnover / business size	• 2019 turnover and tonnes of chemicals sold, number of products, and gross operating profit; annual growth expected in the absence of CSS

[52] Product sectors used are from ECHA, (2015). *Guidance on Information Requirements and Chemical Safety Assessment Chapter R.12*, Version 3.0. Available from: R_12_CARACAL_cross_check_TC (europa.eu)
[53] Typical business responses to regulation that may result in market losses are: substitute the substance, where there is a technically and economically feasible alternative; reformulate away from the substance (or the levels subject to restriction); or seek derogations in the absence of suitable alternatives.

Policy, key business impacts or proxies	Information sought by the survey for evidence on operations in the EU-27 (not an exhaustive list)
	over 10 years; annual growth expected upon adoption of changes to the GRA and CLP over 10 years. Extrapolations are presented thereafter. • Percentage (or sales value) of the affected portfolio that would be in scope for substitution and/or reformulation; and potential derogations from new legislative requirements; expected pass through of potential regulatory burden; considerations of customer responses from price changes based on historical evidence
OPEX	• 2019 annual operating costs; annual growth expected in the absence of CSS over 10 years; annual growth expected upon adoption of changes to the GRA and CLP over 10 years (for the retained business) • Recurring costs of substitution and/or reformulation, and derogations, across different cost categories. Detailed questions associated with administrative burden from CLP especially were also considered in detail
CAPEX	• 2015-2019 average annual total capital investment; annual growth expected in the absence of CSS over 10 years; annual growth expected upon adoption of changes to the GRA and CLP over 10 years • Recurring costs of substitution and/or reformulation, and derogations, across different cost categories
R&D	• Level of operating expenditure/ capital investment devoted to R&D expenditure in the EU-27 and expected evolution in the absence of the CSS; annual growth expected upon adoption of changes to the GRA and CLP over 10 years.
Regulatory burden	• Percent of annual operating and capital costs driven by the EU Chemicals acquis and likely evolution in the absence of the CSS; annual growth expected upon adoption of changes to the GRA and CLP over 10 years • Additional operating and capital requirements driven by the changes to legislation considered
Employment	• 2019 employment; annual growth expected in the absence of CSS over 10 years; annual growth expected upon adoption of changes to the GRA and CLP over 10 years • Potential labour requirements for substitution and/or reformulation; additional administrative activities associated with the potential legislative changes
Other economic impacts	• Consideration of impacts on imports and exports • Qualitative effects on competitiveness

Different approaches were employed to elicit evidence and informed views from businesses (e.g. more explicit or implicit approaches to gather evidence of key potential business impacts) to offer an opportunity to compare and contrast the impacts expected from an analysis of sample responses and review, adjust and/or qualify the results as required.

For example, survey respondents were asked to provide their 2019 turnover and their estimated turnover growth over the next 10 years in the absence of the CSS (i.e. the baseline). Based on this baseline, businesses were asked to consider how they might respond to the potential policy requirements on their affected portfolio, outlined in Section 2.5.1, as follows:

- The percentage and sales value of the affected portfolio that could be substituted or reformulated, based on the evidence available to date
- The percentage of the affected portfolio they may be able to secure derogations for
- The extent to which they may pass through additional regulatory burden through to prices to their customers
- The responsiveness of their clients to price changes.

The data obtained in this consultation is deemed sensitive under competition law. In order to ensure compliance, access to responses to the consultation was limited to study team members from Ricardo and the data was stored in a folder with limited access rights. Cefic, participating associations and their members did not have access to any data, other than that which they submitted themselves, In the analysis of the data, Ricardo followed the statistical rules of Cefic, ensuring that all data was aggregated[54] and anonymised to prevent reverse engineering of data.

Following this, businesses were also asked, explicitly, to provide an estimate for how the adoption of the changes to the GRA and CLP could affect turnover growth over the period. These more explicit views from businesses were only used as a comparison or contrast to the more implicit analysis of impacts that is based on detailed evidence of the affected portfolio and potential business responses.

This two-pronged approach for eliciting evidence and/or informed views from surveyed chemical companies, therefore, allowed the project team to estimate the impact on turnover by triangulating detailed evidence of the affected portfolio and the potential business responses (e.g. substitution, etc.), which is referred as the 'implicit' analysis; and compare and contrast the outputs of said analysis with the explicit views of impact shared by businesses.

Finally, it is noted that 2019 was taken as the baseline year for eliciting evidence of potential impacts from businesses through survey, as 2020 is not considered representative of normal operating conditions of the EU chemicals sector due to the COVID-19 pandemic. This means that the information gathered referred to potential impacts with regards to 2019 business operations. Nevertheless, the information gathered was triangulated with available projections from the European Commission as to the expected recovery from the pandemic to generate a baseline and Impact Assessment that aligns with said expectations.

2.6 Assess the business and economic impacts of the options considered

Business and economic impacts were assessed by employing analytical models and methods in line with Tools #59-62 of the Better Regulation Toolbox. These analytical approaches include statistical techniques for the quantification of policy effects based on evidence collected through a business survey, and statistical techniques for the extrapolation of impacts from the survey sample to the EU-27 chemicals sector.

The **analysis of impacts** was carried out against the baseline (or counterfactual). The following steps were taken:

- **Quantifying the retained business operations for the sample upon adoption of the legislative change:** Assessment of the effects on the size of business operations upon adoption of changes to the GRA and CLP, having identified the portfolio of products that is likely to be affected (i.e., the 'affected portfolio') by these legislative changes. This assessment triangulates responses to multiple survey queries that seek to unveil the potential effects of the legislative changes, after taking into account expected business

[54] The aggregated data used always came from more than five independent companies, the latter being understood as the collection of undertakings whose relations with the company participating to the statistical exercise come within the terms of one or more of the sub-paragraphs of Article 5(4) of the EU Merger Regulation. Any input of less than 5% of the total volume reported by companies was not taken into consideration. Even when aggregated, the data must did not come from one company with more than 70% of the total volume. No price information was included in the report.

responses such as substitution and/or reformulation, successful applications for derogations and changes to product pricing and associated customer responses.

- **Assessing the sample impacts across selected categories** (or proxies)
    - Implicit approach (preferred): An assessment of potential impacts from GRA and CLP based on the triangulation and analysis of multiple queries asking about specific actions that business may take due to the adoption of changes to legislation (e.g. estimating changes in operating expenditure based on estimated changes to the size of operations and the additional burden that would be expected from changes in the manufacturing processes and administrative tasks, among others)
    - Explicit approach (alternative for comparison or check): Using respondents' explicit views as to how much a particular business or economic variable may be affected as a result of changes to GRA and CLP (e.g. estimating changes on operating expenditure based on explicit views of businesses)
    - Whilst a large proportion of the product portfolio of EU Chemicals businesses could be affected by changes in CLP and GRA, there are multiple actions companies could take to mitigate the business impacts of these policy changes. However, these are complex and not easy to assess at a high level and, thus, it is expected that the explicit business views could have limitations. That is why an implicit approach that exploits all of the evidence presented by businesses is preferred.
- **Adjusting these impacts based on the assumed policy implementation timetable:** A weighting has been applied to the number of substances expected to be classified over the next 20 years in order to provide a more informed assumption on impact. The
- includes a number of sources of evidence, including the Registry of CLH intentions[55]; the ED Assessment List[56] and the PBT/vPvB Assessment list[57]. In order to estimate the number of substances that may be classified over the next 10, 15 and 20 years, the following steps have been taken:
    1. Calculate the number of harmonised classifications that have been granted since 2015 and the number of ED and PBT/vPvB decisions that have been made (versus the number of proposals submitted);
    2. Determine the average number of classifications granted per hazard classification since 2015;
    3. Calculate the number of years since 2015 in which hazard classifications have been granted (e.g. for respiratory sensitisers cat. 1, classifications have been granted in 75% of years since 2015);
    4. F2 classifications have been given a probability for classification based on expert judgement on available evidence;
    5. Multiply the average CLH by 10, 15, 20 years to form an estimate of CLH without grouping in order to account for classification of substances over the assessment time period (until 2041);
    6. Calculate the percentage of F1 classifications on the List of Substances to be Regulated to go through if grouped (4% of grouped substances moving forward to CLH, based on the grouping approach used in the 2021 ECHA Integrated Regulatory Strategy report[58]) and the average CLH without grouping;

[55] ECHA, 2021, *Registry of CLH intentions until outcome,* Available from: https://www.echa.europa.eu/registry-of-clh-intentions-until-outcome [
[56] ECHA, 2021, *Endocrine disruptor assessment list*. Available from: https://www.echa.europa.eu/ed-assessment [Accessed on 09/2021]
[57] ECHA, 2021, *PBT assessment list*, Available from: https://www.echa.europa.eu/pbt [Accessed on 09/2021]
[58] ECHA (2021) *Transparent progress in addressing substances of concern. Integrated Regulatory Strategy Annual Report*. Available from: https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2020_en.pdf/646c8559-360d-f6ab-bfb7-02120eab52fa DOI: 10.2823/506792

7. To allow for years where no classifications are granted, for each classification multiply the results so far by the percentage calculated in step 3 e.g. 75% of years with classification decisions for respiratory sensitisation cat. 1..

- **Extrapolating these impacts to the EU Chemicals sector**, which generally included employing the weighted average changes that were estimated for the sample to the EU Chemicals Sector baseline projections, as appropriate (e.g. annual percentage impacts on the sample's turnover of X% are applied to the EU Chemicals sector baseline projections for turnover for the assessment of impacts at the sectoral level)
- **Estimating the potential effects on GDP and employment at EU-27 level**, by considering the indirect and implicit effects of the EU Chemicals sector changes in Gross Value Added and Employment (e.g., employing Input-Output methods)

For each indicator, there were specific approaches, considerations and/or assumptions employed.

2.7 Limitations and quality assurance

The limitations to the impact analysis as well as the quality assurance (QA) approach employed are outlined briefly in this section.

2.7.1 Limitations

There are at least three core limitations to this impact analysis. These are the uncertainty of the policy proposals, the relatively high level of complexity for how these policy options may affect the EU chemicals sector, and the availability of quality data.

First, the policy proposals remain uncertain and under development. This means that the policy details are not yet clear, and assumptions have been required. Policy assumptions have been quality assured to ensure they reflect the policy debate. As discussions are ongoing, the assumptions made in this assessment may not accurately reflect the regulatory changes that enter into force. However, the assessment carried out and its outputs are highly dependent on these assumptions and, therefore, reflect the same level of uncertainty.

Secondly, the data available has limitations. There is limited historical evidence of relevance, given that the policy options considered for future implementation go over and above any other policies implemented in the EU and internationally. It has been, therefore, necessary to rely on consulting businesses to gather evidence as to the potential actions they may take as a response to the legislative proposals and the associated costs and benefits, as pertinent. The data gathered through the consultation exercises is limited by the sample of respondents and their understanding and assessment of how the policies considered may affect their operations. The sample, in numbers, is statistically representative, with a margin of error +/- 10% (Section 2.5). However, the sample also comprises a disproportionate number of large firms. On the one hand, this is not deemed a significant issue since around 70% of the sectoral output is generated by large firms. On the other, 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.

Thirdly, the policies under consideration will affect the EU chemicals sector in multiple and complex ways. This study has limitations by design, in that it is focussed on chemicals business impacts and associated knock on-effects (excluding other social and environmental, as well as economic impacts driven by other dynamics outside of the chemicals sector). In this context, two key impact drivers of impact on businesses were considered: direct and indirect restrictions of use or manufacture of chemicals; and additional regulatory burden, thus potentially affecting the economic viability of certain operations. The extent to which these impacts affect sub-sectors and businesses, and how these businesses may respond, will vary, including whether or not business 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. Therefore, an informed

simplification of the impact pathway, based on the project team expertise, was introduced, with inherent limitations.

The analysis, therefore, assumes that adding hazard classes to CLP coupled with an extension of the GRA will lead to further restrictions to consumer and professional-use products based on harmonised classification of substances. These restrictions would lead to the discontinuation of the use and/or manufacture of the affected product unless it can be substituted or reformulated, or derogations from restrictions can be secured. These business responses are estimated to result in additional costs, when compared to the baseline, albeit it is assumed that they would be economically viable (given the way in which this evidence was collected/ design of the survey).

Changes to CLP on their own will also lead to increases in regulatory burden, which could affect the economic viability of some operations. The regulatory burden is quantified, however, whether or not these additional costs would affect the viability of some business operations is not (although this is unlikely). Indirectly, however, some products may be affected by reputational implications of the new hazard classifications and restrictions under the GRA. These implications are assumed to affect up 25% of the product portfolio that is only affected by CLP changes, and are estimated to lead to the discontinuation of the use and/or manufacture of these products unless they can be substituted or reformulated. This assumption has not been identified in the study, but it has been developed based on expert input.

Moreover, there are also a number of known unknowns, such as how technological progress may affect the EU chemicals sector and whether and how this would interact with the impacts of legislation. Further, international trade and competitiveness are likely to affect the EU chemicals sector but these effects are not considered in depth primarily due to limitations in the evidence available. These are further sources of uncertainty. Although an estimate of how grouping may expediate regulatory action has been included in the weighting of hazard classifications, this is based on limited evidence and so we may actually see that the grouping of chemicals results in much faster regulatory management.

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

2.7.2 Quality assurance

A number of approaches were employed to assure the methodology, analysis and outputs throughout the project, including with experts within the project team. This included:

- **Baseline**: The methodology and analysis of publicly available data to produce baseline projections for business and economic indicators was reviewed by an expert economist. Feedback was provided and considered to produce final outputs. The data available is limited and it has not always been possible to take into account complex or emerging trends in the sector and the EU-27 economy, such as e.g. technological progress and how this may affect the evolution of employment per unit of turnover. This introduces significant uncertainty to the projections. However, it was concluded that these estimates offer a practical and reasonable counterfactual against which to consider the effects of policy options in this context of uncertainty.
- **Policy assumptions**: An ex-ante assessment of impacts requires concrete and specific policy options. A number of informed assumptions (Section 4.2) were developed based on the ambitions outlined by the EC in the CSS. These assumptions were checked with chemicals policy experts and discussed with a group of experts from Cefic. The output provides an informed view of the types of policies that are being considered by the European institutions and their potential timetable.
- **Consultation design and implementation**: Consultation questionnaires, including a bespoke business survey, were designed and reviewed by experts in chemicals businesses, chemicals policy and Impact Assessments following the European Commission Better

Regulation Guidelines. Technical experts from Cefic and their membership were also engaged to ensure that the approach was proportionate and practical whilst meeting the project's needs, including in terms of the number and quality of responses that could be expected. More than three rounds of feedback were implemented to quality assure the design of the questionnaires and strike a balance between the details required and the practicalities of the time and resources available to complete and subsequently assess the data gathered.

- **Data gathered:** The Consultation questionnaires produced the core data employed for the quantitative Impact Assessment. The data 'cleaning' and parametrisation was checked for any structural challenges and any feedback was fed through the final dataset analysed. The data was checked, reviewed and tested using standard visualisation techniques and exploring the mean, median and standard deviation or spread of responses to a random selection of survey responses. Where any potential issues were identified, the project team followed up with a random selection of respondents to develop an informed approach to resolve these potential issues. For example, when responses suggested big annual changes in key performance indicators such as turnover, the interpretation of the questions were checked to corroborate whether answers referred to annual or cumulative changes over a period of 10 years. Tests were carried out for potential outliers. The final dataset, therefore, represents the best available evidence from businesses as to their baseline operations and potential responses to the policy options considered.
- **Impact analysis**: The project team carried out an analysis of selected impact categories, relying primarily on the data collected by consulting Cefic and partner associations members. This analysis was primarily done in MS Excel and complemented by statistical analysis in Stata. There were three rounds of quality assurance of this work. The approach to assessing impacts was reviewed by chemicals policy and Impact Assessment experts and iterated. Following this, the analysis carried out in MS Excel was also reviewed. The flow of information, the implementation of the methodology, and the individual formulae were checked and corroborated. The outputs were also contrasted with hypothesis and, where potential issues were identified, a more in-depth review was carried out to ensure the analysis was carried out effectively.

The assessment and outputs presented in this report have, therefore, been reviewed and checked by a number of experts and represents an informed view of the potential impacts of the policy options considered, caveated by the limitations outlined and inherent to an ex-ante Impact Assessment.

3 Context and Baseline Scenario

This section provides insight into the context surrounding the policy options considered in this assessment and the baseline, "Do Nothing", scenario.

In order to frame the policy options within their wider context, there is an overview of the EU chemicals legislative framework and the EU Green Deal, with subsequent sections outlining hazard classification and communication and risk management approaches.

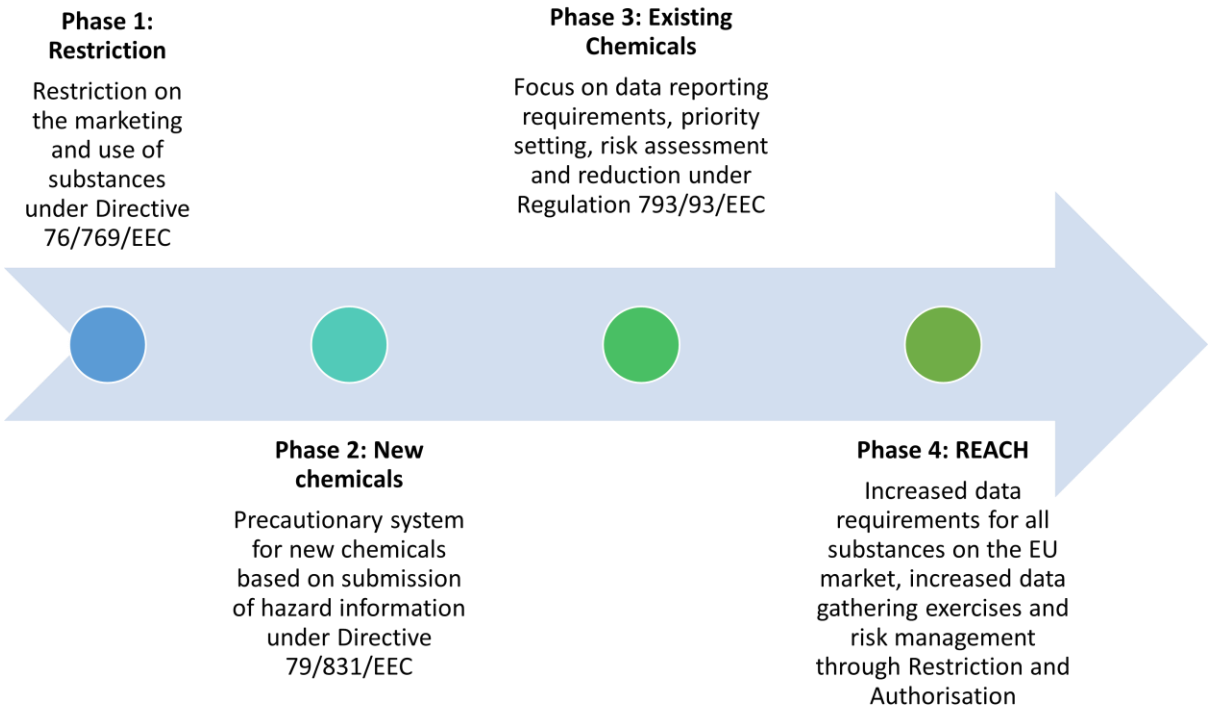
The final sub-section provides the business context, exploring the EU chemicals industry and outlining the baseline scenario for which business impacts are measured against.

3.1 General Overall Policy Context

Chemicals are essential in our everyday lives and the positive impacts of their availability and use are seen on a daily basis. An example of which is the ability to sanitise our hands and surfaces during the COVID-19 pandemic, which would not have been possible without the use of biocidal products. There is, however, evidence to support concerns surrounding the negative impacts of chemicals on human health and the environment and the need for stringent regulation of their manufacture, use and disposal.

The EU has regulated the exposure of humans and the environment to hazardous substances for over 50 years, with the original Community legislation relating to classification of substances being adopted in 1967 (the Dangerous Substances Directive - 67/548/EEC) and extended to preparations (now termed mixtures) in 1988 (88/379/EEC). Chemicals policy has changed over the last half century from being reactive to evidenced risks to proactively identifying hazards and potential risk and mitigating this. Figure 3-1 illustrates the four chronological phases of EU chemicals policy identified by Haigh (2016).

Figure 3-1 Chronological Phases of EU Chemicals Legislation[59]

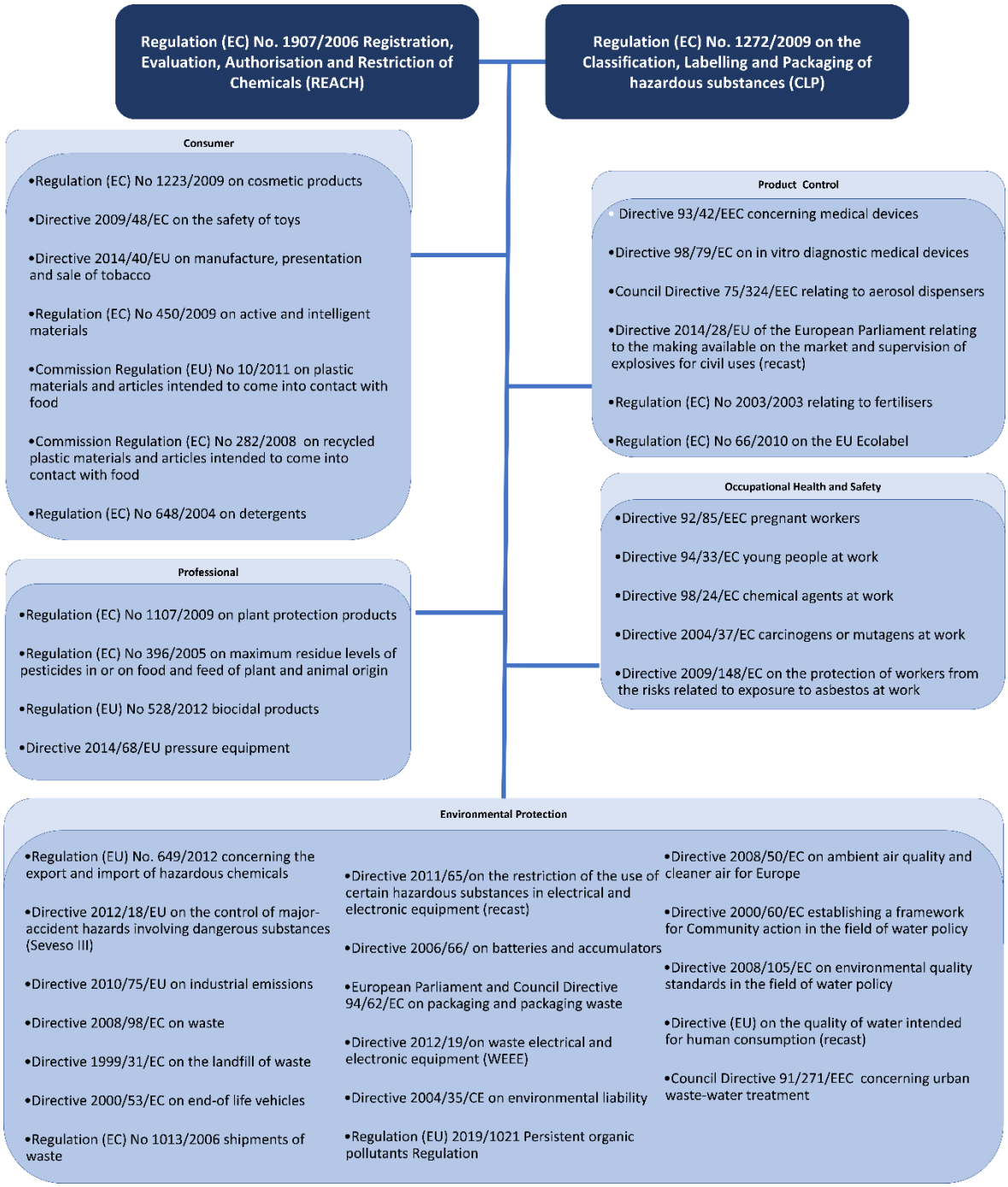


[59] Nigel Haigh (2016) EU environmental policy: its journey to centre stage. *Journal of Environmental Law,* Volume 30, Issue 1, p. 172–174. Available from: https://doi.org/10.1093/jel/eqy002

The EU chemicals acquis has evolved, with many pieces of legislation being developed in parallel to those outlined above. The comprehensive EU chemicals legislative framework now comprises around 40 pieces of legislation, including but not limited to: Regulation (EU) No. 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[60]; Regulation (EC) No. 1272/2009 on the Classification, Labelling and Packaging of hazardous substances (CLP)[61]; sector specific legislation such as the Directive 2009/48/EC on Toy Safety[62], Regulation (EC) No. 1223/2009 on Cosmetics Products[63], Regulation (EU) No. 528/2012 on Biocidal Products[64], and Regulation (EC) No. 1107/2009 on Plant Protection Products[65]; health and safety of workers such as the Directive 98/24/EC on chemical agents at work[66]; and environmental protection legislation such as the Directive 2008/98/EC on Waste[67] and Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals[68]. Figure 3-2 provides a non-exhaustive overview of the EU chemicals legislative framework.

[60] Ibid footnote 46
[61] Ibid footnote 41
[62] *Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.* The Official Journal of the European Union. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009L0048-20210521
[63] *Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast)*. The Official Journal of the European Union. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1223-20210823
[64] *Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.* The Official Journal of the European Union. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20210610
[65] *Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.* The Official Journal of the European Union. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1107-20210327
[66] *Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).* The Official Journal of the European Union. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01998L0024-20190726
[67] *Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.* The Official Journal of the European Union. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02008L0098-20180705
[68] *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 (recast).* The Official Journal of the European Union. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0649-20200901

Figure 3-2 Overview of EU Chemicals Legislative Framework



As the overarching pieces of chemicals legislation, the REACH Regulation and CLP Regulation introduced different regulatory management measures for substances, mixtures and, in the case of REACH, articles, which display a range of hazardous properties, with more restrictive risk management for those which are deemed to be of highest concern. Despite the increased regulatory management of hazardous substances, recent regulatory reviews have noted that more needs to be done in order to ensure a high level of protection to human health and the environment[69,70,71,72,73]. This is evidenced by human biomonitoring studies in the EU having identified a growing number of hazardous chemicals in human blood and tissue, including pesticides, biocides, heavy metals, plasticisers, flame retardants and pharmaceuticals. There have also been over 200 synthetic chemicals detected in umbilical cord blood, some of which are used in consumer products and food packaging. In 2017, it was reported that 3.5 million sites around Europe are already contaminated by hazardous substances, which may have not only severe environmental consequences but also economic consequences due to the cost of remediation and loss of natural resources.[74]

3.1.1 The European Green Deal and the Chemicals Strategy for Sustainability

The European Green Deal[75] was launched in December 2019 and sets out the European Commission's commitment to tackling climate and environmental-related 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 EU Green Deal recognises that without good environmental health, human health suffers and despite decades of regulatory action to prevent air, soil and water pollution, more needs to be done to protect from environment-related risks and impacts.

The aim of the Green Deal growth strategy is to "*transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy*"[76]. This includes the aims to:

- Become climate neutral by 2050 through net-zero emissions of greenhouse gases by 2050.
- Protect, conserve and enhance the EU's natural capital and protect human and animal health by cutting pollution and decoupling economic growth from resource use
- Help companies to innovate and become world leaders in clean products and technologies and facilitating a circular economy
- Ensure a just and inclusive transition.

In order to meet this zero-pollution ambition for a toxic-free environment and climate neutrality, all EU actions and policies will need to contribute to the EU Green Deal objectives. The key themes of the EU Green Deal are outlined in Figure 3-3.

[69] European Commission (2018) *Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee: Commission General Report on the operation of REACH and review of certain elements: Conclusions and Actions.* SWD(2018) 58 final. COM(2018) 116 final. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN
[70] Ibid footnote 36
[71] Ibid footnote 37
[72] Ibid footnote 38
[73] 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
[74] Ibid
[75] 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
[76] Ibid

Figure 3-3 Key Themes of the EU Green Deal

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*"[77]. 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.

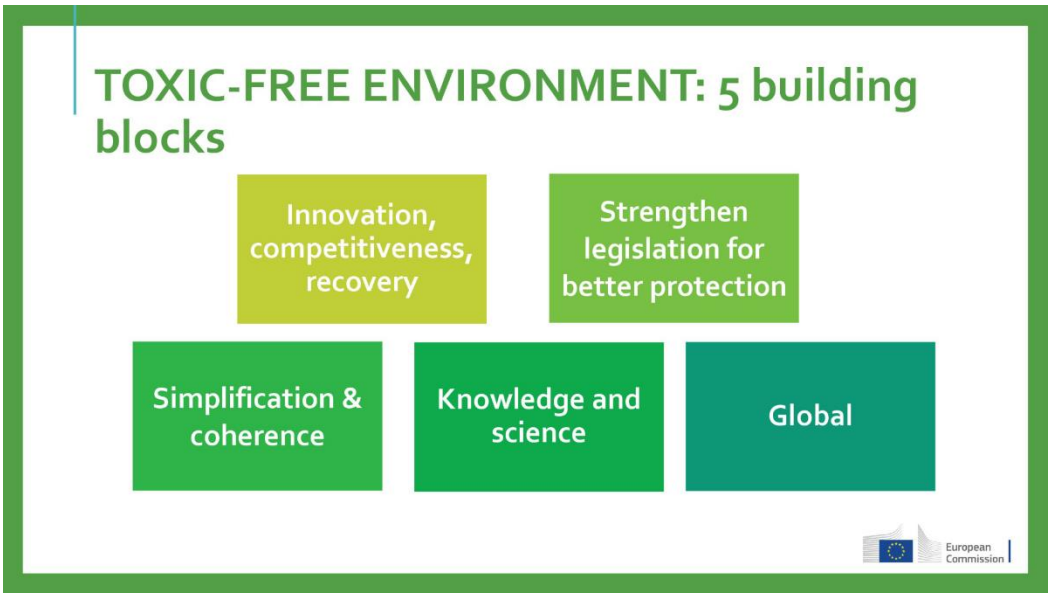
As outlined in Section 1, the EU Commission's Chemicals Strategy for Sustainability introduced a new long-term strategy for European chemicals policy. It is the first step in meeting the zero-pollution ambition for a toxic-free environment outlined in the EU Green Deal and is complementary to other European Green Deal strategies and initiatives, such as the biodiversity and the farm to fork strategies; the hydrogen, methane and pharmaceuticals strategies; and the European Industrial strategy. With 84% of Europeans concerned about the impact of the chemicals in their products on their health, and 90% concerned about the impact of chemicals on the environment, the CSS is key to responding to these worries with the aim to:

- Ensure a greater level of protection of human health and the environment from hazardous chemicals;
- Increase innovation of safe and sustainable chemicals;
- Facilitate and encourage the transition to chemicals that are safe and sustainable by design.[78]

In order to meet these aims, the CSS has outlined key actions (Figure 3-4).

[77] Ibid footnote 75
[78] European Commission (2020) *Chemicals Strategy Factsheet.* Available from: https://ec.europa.eu/environment/pdf/chemicals/2020/10/chemicals-strategy-factsheet.pdf doi:10. 2779/221541

Figure 3-4 Key Actions of the EU Chemicals Strategy for Sustainability[79]



To meet the aims of the CSS, innovation for green transition in the chemicals industry and its value chains is vital. But in order 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.[80]

3.2 Policy Context Specific to Hazard Classification and Communication

Hazard communication through the classification, labelling and packaging of substances and mixtures in the EU is regulated by the CLP Regulation. The CLP Regulation entered into force in 2009, amending the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC). Since 1 June 2015, CLP is the only legislation in force in the EU that regulates the classification and labelling of substances and mixtures. CLP is based on the United Nations' Globally Harmonised System (UN GHS), which was proposed at the UN Conference on Environment and Development (UNCED) in 1992, as a response to the need to develop a universal system to identify and communicate the presence of hazardous chemicals.[81] Although the EU had already implemented a strong and robust system of classification and labelling, different jurisdictions around the world had used different systems for the classifications and labelling of diverse preparations and mixtures of chemicals.[82] Despite many of the hazard communication requirements

[79] European Commission (2021) EU Chemicals Strategy for Sustainability. Slide 4. Presentation to APPLiA: The new EU Chemicals Strategy for Sustainability: building a game-changing framework for Europe. 4th March 2021. Available at: https://www.applia-europe.eu/applia-media/webinars/366-at-the-crossroads-between-chemical,-product-and-waste-policies-the-new-eu-chemicals-strategy-for-sustainability
[80] Ibid footnote 33
[81] UK Health and Safety Executive. (n.d.) *Background: Globally Harmonized System (GHS)*. Available from: https://www.hse.gov.uk/chemical-classification/legal/background-directives-ghs.htm
[82] European Commission. (n.d.) *Classification and labelling (CLP/GHS).* Available from: https://ec.europa.eu/growth/sectors/chemicals/classification-labelling_en [Accessed 10/09/2021]

being similar, some regions saw significant differences. More detail on the UN GHS can be found in Annex 1.

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 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.[83]

The starting point for hazard communication is classification. Physico-chemical and (eco)toxicological data are used to identify whether a substance or mixture meets the classification criteria outlined in CLP for physical, human health and environmental (and additional) hazards. Classification of a substance involves both self-classification and harmonised classification and labelling (CLH). Self-classification is performed by manufacturers, importers or downstream users for all relevant hazard classes for which there is no harmonised classification but the substance presents hazardous properties. Where no current harmonised classified (Annex VI entry) exists, all relevant hazard classes must be assessed and self-classification applied where the criteria are fulfilled. Mixtures are subject to self-classification only, according to calculation rules provided in the CLP Regulation (generic concentration limits, specific concentration limits and occasionally testing).

Harmonised classification is legally binding and, in order to ensure harmonised and adequate risk management throughout the EU, it is performed for hazards of highest concern (CMR, respiratory sensitisers) and for other endpoints on a case-by-case basis. Harmonised classifications are listed in Annex VI of CLP and once a CLH enters into force it must be applied by all manufacturers, importers and downstream users.

A CLH proposal can be submitted by a Member State Competent Authority (MSCA), manufacturer, importer or downstream user of a substance, in cases where:

- The substance is a CMR or respiratory sensitiser
- It is justified that a classification for a substance at EU level is needed for other hazard classes
- There is a need to add one or more new hazards classes to an existing entry.

Proposals for revision of an existing harmonised classification or harmonised classification of an active substance in biocidal or plant protection products can only be submitted by MSCA.

3.2.1.1 EU adoption of United Nations Globally Harmonised System of Classification and Labelling of Chemicals

The UN GHS has allowed for a greater protection of human health and the environment at an international level and has provided a classification framework for countries that did not have a

[83] Ibid footnote 39

classification and labelling system.[84] The UN GHS is based on a building block approach which provides participating countries with the hazard classes and categories for which they can form their regulatory approach to hazard classification and communication. [85]

Under the building block approach, different jurisdictions have chosen which GHS hazards classes and categories (Cat.) to implement through their own regulations. The building blocks selected by the EU are implemented by the CLP Regulation and can be summarised in Table 3-1[86]

[84] United Nations Economic Commission for Europe (UNECE). (n.d.). *About the GHS*. Available from: https://unece.org/about-ghs [Accessed on 09/2021]
[85] Di Prospero Fanghella, P., and Catone, T. (2011). *The CLP Regulation: origin, scope and evolution*. *Ann Ist Super Sanità*, 47(2), pp. 126-131. Available from: https://www.scielosp.org/pdf/aiss/2011.v47n2/126-131/en
[86] Ibid footnote 39

Table 3-1 UN GHS Building Blocks Adopted by CLP Regulation

Physical Hazards	Health Hazards	Environmental Hazards
Unstable explosives	Acute toxicity, Cat. 1 - 4	Long-term hazards to the aquatic environment, Cat. 1 - 4
Explosives, Div1.1 - Div1.6	Skin corrosion/irritation, Cat. 1, 1A, 1B, 1C, 2	Acute hazards to aquatic environment, Cat. 1
Flammable gases, Cat. 1A, 2	Serious eye damage/eye irritation, Cat. 1, 2	Hazard to the ozone layer
Flammable gases, Cat. 1A (Chemical unstable gases, Cat. A and B)	Respiratory sensitisation, Cat. 1, 1A, 1B	
Aerosol, Cat. 1 - 3	Skin sensitisation, Cat. 1, 1A, 1B	
Oxidizing gas	Germ cell mutagenicity, Cat. 1A, 1B, 2	
Gases under pressure, compressed, liquified, refrigerated liquified & dissolved	Carcinogenicity, Cat. 1A, 1B, 2	
Flammable liquids, Cat. 1 – 3	Reproductive toxicity, Cat. 1A, 1B, 2, & lactation	
Flammable solids, Cat. 1, 2	STOT single exposure, Cat. 1 - 3	
Self-reactive substances or mixture, Type A - Type G	STOT repeated exposure, Cat. 1 - 2	
Pyrophoric liquids	Aspiration hazard, Cat. 1	
Pyrophoric solids		
Self-heating substances or mixtures, Cat. 1, 2		
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 1 - 3		
Oxidizing liquids, Cat. 1 - 3		
Oxidizing solids, Cat. 1 - 3.		
Organic peroxides, Type A - Type G		
Corrosive to metals		

Several UN GHS building blocks were not adopted by the CLP Regulation on the basis that the potential benefits would be disproportionate relative to the costs of classification and labelling to industry and consumers[87] . However, chemicals which display the hazardous properties of building blocks which were not adopted may still be included in the Classification and Labelling Inventory (CLI).

3.3 Policy Context Specific to Current Risk Management Approaches

3.3.1 The Generic Risk Approach

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) [88]. 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 publication of the Chemical Strategy for Sustainability (CSS) included use of the terminology '*generic approach to risk management'*, hereby referred to as GRA. The GRA is described in the CSS as follows:

> *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).* [89]

The GRA is utilised by a number of pieces of the EU chemicals legislation and is seen as reflective of the precautionary principle. The precautionary principle has been a recurring influence in the development of EU chemicals legislation for more than twenty years[90]. When applied, the precautionary principle aims to produce an effective and efficient regulatory response to protect human health or the environment without the need for conclusive data. This approach is commonly used in chemicals legislation due to the difficulties in determining the risk posed by a substance, especially when a substance is widely used as use conditions are less easily controlled.

The GRA covers certain chemicals for regulatory action based on the substance's intrinsic properties (e.g. carcinogenic, mutagenic, reprotoxic (CMR), persistent, bioaccumulative, toxic (PBT), endocrine disrupting etc.), without the need, or possibility, to assess and account for risk as a result of exposure to the substance of concern.[91]

The GRA is generally applied across EU chemicals legislation in line with five main scenarios[92]:

- If there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management.
- In widely dispersive or open applications which result in a significant exposure of humans or the environment.

[87] Ibid footnote 36
[88] 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)
[89] Ibid footnote 33
[90] Ibid footnote 37
[91] Ibid footnote 88
[92] Ibid footnote 88

- In applications where the exposure is considered to be more difficult to control and monitor.
- In applications resulting in exposure of vulnerable groups (e.g. children)
- To prioritise the risk assessment of certain chemicals and under certain conditions.

The best examples of the implementation of the GRA are the ban on the use of CMRs cat. 1A & 1B in substances and mixtures to be supplied to the general public, or the ban on CMRs cat. 1A & 1B in cosmetic products.

Many chemicals are known to cause serious damage to human health and the environment[93] and an increase in certain health problems have been partially attributed to the exposure to these chemicals.[94] To provide rapid protection from specific risks, automatically triggered risk management measures are enforced via the GRA. Within EU chemicals policy, the GRA is an example of a preventive action.[95] It allows for a potential risk to be prevented quickly, to enable concerns to be addressed without putting humans or the environment at risk. Although it should be noted that a risk is not always present when basing risk management on intrinsic properties only, with no consideration of exposure. The GRA is applied under Article 68(2) of REACH and through sector specific legislation. Table 3-2 provides an overview of whether, for different hazardous classifications, the GRA is applied for consumer and/or professional use products as an approach in six pieces of chemical legislation.

[93] European Commission, (2020). *Chemicals are everywhere.* [Online] Available from: https://ec.europa.eu/environment/chemicals/index_en.htm
[94] Ibid footnote 73
[95] Ibid footnote 88

Table 3-2 Current Application of Generic Approach to Risk Management in Key Legislation for Professional and Consumer Products

Legislative Act	Carc 1A/1B	Muta. 1A/1B	Repro. 1A/1B	PBT	vPvB	ED	Resp sens.. 1	STOT RE 1	STOT SE 1	Carc. 2	Muta. 2	Repro. 2
Approximate number of substances (2021)	932	428	206	88		89	116	182	14	200	144	148
REACH Restriction (Article 68(2))	Co	Co	Co									
Regulation (EC) No 1223/2009 on cosmetic products	Co	Co	Co							Co	Co	Co
Directive 2009/48/EC on the safety of toys	Co	Co	Co							Co	Co	Co
Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food	Co	Co	Co									
Regulation (EC) No 1107/2009 on plant protection products	Co P	Co P	Co P	Co P	Co P	Co P						
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products	Co P	Co P	Co P	Co P	Co P	Co P	Co	Co	Co	Co	Co	Co
Regulation (EU) 2017/745 on medical devices	Co P	Co P	Co P			Co P						

Key	
Co	Consumer Products
P	Professional use Products

3.3.2 The Specific Risk Management Approach

Specific risk assessments (SRAs) require hazard identification in combination with a use and potential exposure assessment before regulatory action can take place[96].

Specific risk assessments are described in the CSS as:

> *'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'*[97]

SRAs are performed on a case-by-case basis.[98] This approach is typically applied to substances whose use may not necessarily or obviously lead to widespread and difficult to control exposures and/or where the hazard properties of the substance are of lesser concern.[99] The simultaneous considerations of the substance's physical and chemical properties as well as intended use, aims to account for both hazard and exposure in order to assess the risks more appropriately.

EU chemicals legislation incorporates the specific approach in two main ways: [100]

- **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 it will be added to a list of authorised substances for specific uses where no suitable alternative exists or the risk can be controlled. The trigger for Candidate Listing is based on the generic risk approach, but the authorisation process is an example of specific risk assessment.
- **Leading to Restriction:** the assessment is carried out by either the government authorities or the manufacturers. 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.

3.3.3 Comparison of Risk Management Measures

These two approaches – of the generic risk approach and specific risk assessment – are contrasting in their execution, their exposure considerations, and occasionally in their outcomes. The GRA is an automatic trigger, with no further assessments or considerations necessary once CLH has been granted, thus producing a streamlined risk management approach. The efficiency of the GRA may be deemed to be appropriate due to the potential negative health and environmental impacts of the hazard classifications for which it is currently applied.

The SRA approach entails risk assessments which consider the hazardous properties and use of a substance, as well as the possible exposure scenarios. This approach takes time but delivers a tailored risk management response. Both approaches consider exposure in some form, but this consideration within the GRA is generalised. This generalisation allows the GRA to quickly address harmful exposure scenarios, such as widespread exposure, non-controllable exposure, and exposure to vulnerable groups. The SRA approach does not make generalisations such as these and the assessment covers the substance use and possible exposure routes in detail. Nevertheless, it could be assumed that the outcome for many substances of high concern (e.g. CMRs), whether via the GRA or the SRA approach, would be the same, and the overall aim of each approach is to protect human health and the environment.

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[96] ChemSec, (2020). *5 aspects that the Chemical Strategy must include.* [Online]
Available from: https://chemsec.org/app/uploads/2020/04/Chemicals-strategy-ChemSec-view-April-2020.pdf
[97] Ibid footnote 33
[98] Ibid footnote 88
[99] Ibid footnote 88
[100] Ibid footnote 37

Both approaches are enforced across the breadth of chemical legislation, and there are many examples where individual pieces of chemicals legislation make use of both SRA and GRA (see below).

GRA in practice: Under the Cosmetic Products Regulation certain substances are banned from use in cosmetics regardless of specific exposure levels using the GRA. This includes any substance classified as carcinogenic, mutagenic or toxic for reproduction (CMR) categories 1A/B and 2*. The rationale being that direct exposure of humans is occurring by the application of a cosmetic product.[101]

SRA in practice: The Cosmetic Products Regulation also applies the specific risk management approach to determine lists of authorised substances and restrictions on the use of particular substances in certain situations. [102]

**Subject to derogations*

3.4 Benefits and disadvantages of the GRA and SRA

Given that the two main approaches to risk management differ in their application and the way in which they trigger risk management measures, they entail different advantages and disadvantages. Both the 2017 Fitness Check[103] and the 2017 Fitness Check+[104] discussed the key advantages and drawbacks associated with the GRA and SRAs these are compiled below in Table 3-3.

Table 3-3 Comparison of the two main risk management approaches.

Generic Risk Approach	Specific Risk Assessments
• A clear signal to all the actors involved (enforcement authorities, industry and downstream users) on the types of hazardous substances which should be avoided • The risk management decision making process results in a more predictable outcome (compared to SRA) which may stimulate innovation • More appropriate for substances of higher concern and where vulnerable populations are at risk and/or cannot be protected through e.g. training or protection equipment (e.g. children under the Toy Safety Directive) • Quick process and can be less financially burdensome, particularly for SMEs due to lack of data requirements.	• Allows for a more targeted assessment of the exposures and thus risks according to the intended use. • Considerations of the products' physiochemical properties contributes to a more appropriate identification of exposure and of risk management measures. • Generally considers socio-economic assessments to cover the full costs and benefits of the consequential risk management measures.

Source: 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,* Wood, 2017. Study supporting the Fitness Check on the most relevant chemicals legislation ("Fitness Check +")

The difficulties faced by industry and consumers as a consequence of the current risk management approaches can be sourced to two main deficiencies, a lack of consistency and a lack of specificity.

The current risk management methods have been criticised as inconsistent, which has been linked to an increase in uncertainty hindering competitiveness and innovation.[105] A consistent approach could

[101] Ibid footnote 88
[102] Ibid footnote 88
[103] Ibid footnote 88
[104] Ibid footnote 37
[105] Ibid footnote 88

streamline the administrative requirements of industry, increasing the predictability of approvals and restrictions. This predictability would benefit innovation within the sector by providing a clear guide for decision making. The inconsistencies highlighted relate to the variation in hazard classifications which can trigger the GRA or an SRA, as well as the numerous different derogations applied in combination with the GRA across the current EU chemicals legislation.[106]

Many also argue that the GRA is an inappropriate or disproportionate approach for certain substances. By initiating restrictions based on hazards only, substances have been banned without an evaluation on the possible routes of exposure. This can lead to the ban of chemicals that are valuable to society, which, in cases where there is no or limited exposure, may in turn negatively affect the overall aim of protecting human health and the environment as a result of the unnecessary removal of substances from the market that are essential. Further to this, the substitution of a substance restricted via the GRA could lead to the use of lesser known, harmful chemicals.[107]

In contrast, the difficulties associated with the use of the specific risk assessments lies mainly with the process, not the outcome. The vast data requirements are a large burden for manufacturers and government bodies. As the SRA requires a risk assessment it is a data intense process for which the financial and data burden can disproportionately affect SMEs. The quality of this information has also been criticised. Data and testing requirements can be inconsistent or unclear, with testing guidelines being slow to adapt to new advances, particularly for mixtures which can lead to the assessment of poor-quality data.

Criticism also lies with the modelling of exposure scenarios as the ability to accurately assess all possible exposure scenarios of a substance is notoriously difficult.[108]

3.5 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 will be taken as reference throughout the analysis of business impacts in Section 5. Differences between large businesses and SMEs are considered where possible and applicable, as well as a description of the business context and baseline projections of the two largest contributing countries to the EU chemicals sector, namely France and Germany.

3.5.1 Sectoral scope and context

European chemicals companies carry out a wide range of activities that affect the lives of European residents 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 chemical industry that is going to be used throughout this document corresponds to 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*."[109]

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[110], 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

[106] European Commission, (2021). *Inception impact assessment - Ares(2021)2962933 - Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals.* Available from: Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment (europa.eu)
[107] Ibid footnote 88
[108] Ibid footnote 37
[109] Ibid footnote 45
[110] All monetary figures are expressed in 2020 constant euros.

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[111].

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[112].

Extra-EU exports of the European chemicals sector amount to €95 billion and represent 11% of total world chemicals exports[113]. 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.

A 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU chemical industry[114] suggests that the regulatory burden affecting the sector represents over 2% of their turnover[115]. This 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, yields regulatory burden. Although Technopolis Group, VVA. (2016) excludes regulatory costs from changes in the classification of substances, they are included in the assessment in this report.

Finally, regulatory burden is variable 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.

3.5.2 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%[116]. The contraction in European economies experienced during the pandemic is expected to be rapidly overcome, according to European Commission's estimations of GDP recovery[117], 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[118]. Most recently, over the last five years, the EU-27 sector's contribution to world exports has declined from 13% to 11%.

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 EU

[111] Eurostat (2021), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 09/2021]
[112] Ibid footnote 88. All employment figures are expressed in FTE units.
[113] 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]
[114] 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
[115] 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.
[116] Ricardo own estimations from econometric regressions relating the output of the EU-27 chemicals sector to EU-27 GDP and population.
[117] 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
[118] Cefic (2021), *Facts and Figures*. [online] Cefic Available from: 2021 Facts and Figures of the European Chemical Industry - cefic.org [Accessed 09/2021]

Chemicals Strategy for Sustainability would not be implemented. These baseline scenario projections and trends are considered for seven indicators or themes:

- Turnover
- 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.

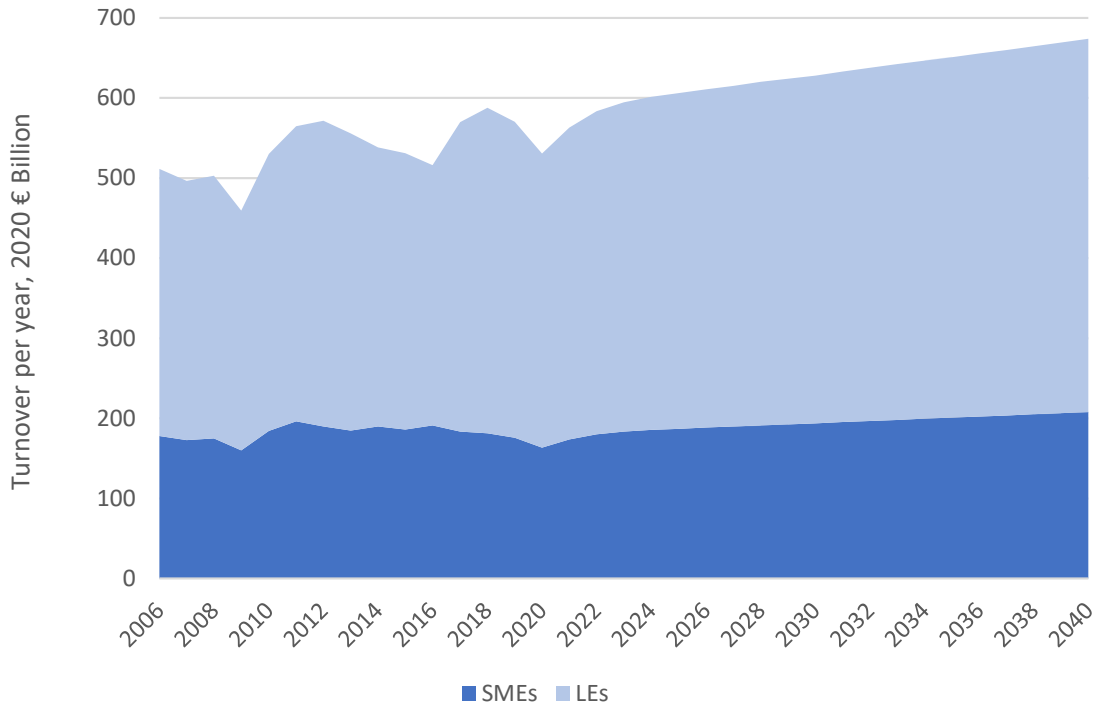
3.5.2.1 Turnover of the EU-27 chemicals sector

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 and is depicted in Figure 3-5 below. 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.

Over the last decade, large enterprises have driven the growth of the EU chemicals sector. 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.

As a result, the share of turnover from large enterprises has increased over time and reached 69% of total sectoral output. 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. The split of turnover, or sales, between large enterprises (LEs) and SMEs is also shown below in Figure 3-5.

Figure 3-5 Total turnover and breakdown between SMEs and LEs of the EU-27 chemicals sector



Source: Ricardo analysis based on Eurostat data

3.5.2.2 Value added of the EU-27 chemicals sector

The Gross Value Added (GVA) of the chemicals sector, more technically 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).

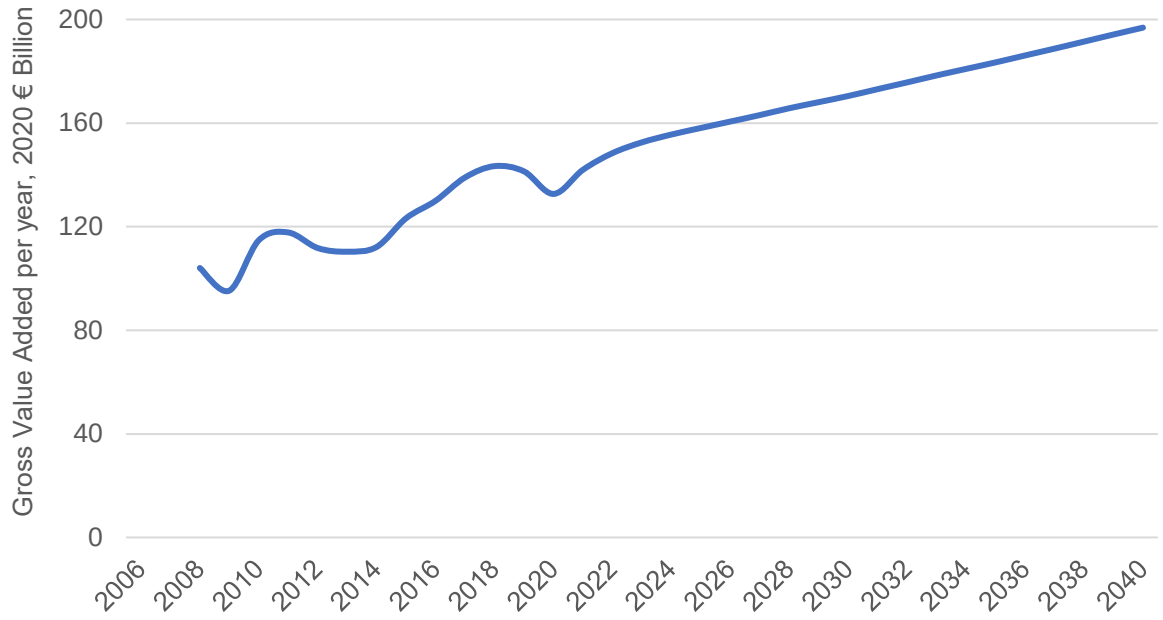
The GVA of the sector amounted to around €140 billion in 2019, equivalent to over a quarter of its economic output. This has increased steadily over the last decade at a CAGR of 4%, which is twice as fast as the sector's output growth. Two trends have potentially contributed to this:

- Intermediate costs have grown at a slower pace than output (1.5% vs 2.1% per year) over the last decade, whilst the chemicals sector reduced its energy intensity by an estimated 22% 119.
- The sector's expenditure on R&D has grown more rapidly than output (2.7% vs 2.1%). The sector's innovation has likely translated into higher value added in the sector.

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

In the baseline scenario, these trends are assumed to continue into the future, as shown below in Figure 3-6, with GVA growing faster than output to 2040.

Figure 3-6 Gross value added of the chemicals sector in the EU-27



Source: Ricardo analysis based on Eurostat data

3.5.2.3 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" [120]. 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

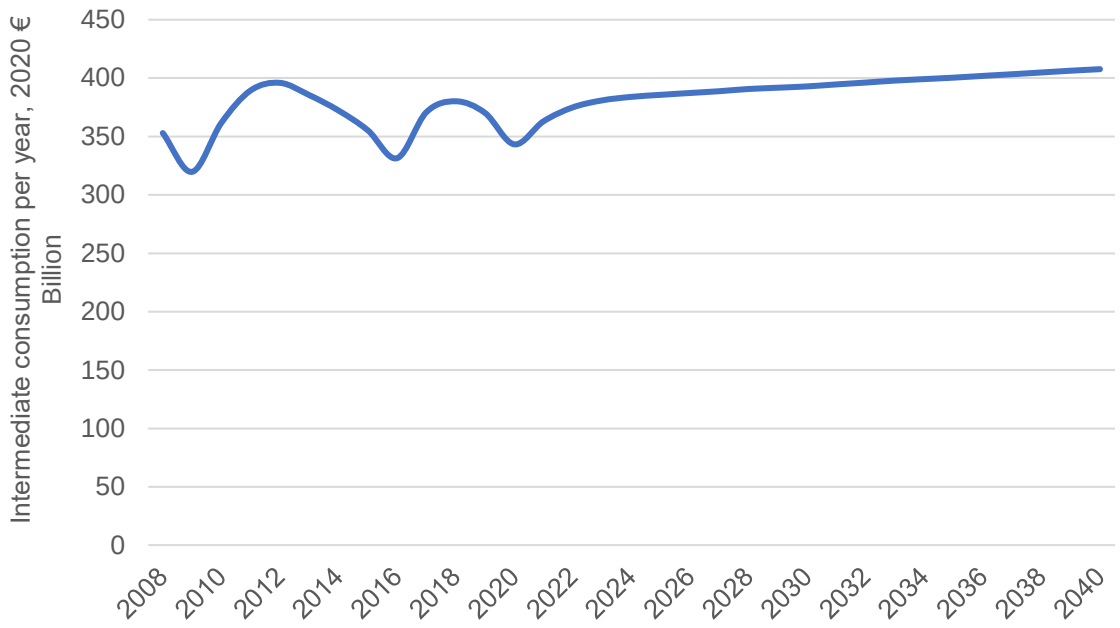
[119] Ibid footnote 118
[120] Eurostat, (2021). *Glossary* [Online] Eurostat. Available from: Glossary:Intermediate consumption - Statistics Explained (europa.eu)

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. 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[121].

This trend is assumed to continue, as showcased in Figure 3-7 below. Further and significant improvements in energy efficiency are still expected through to 2050, partly driven by the ongoing efforts from industry and European and national level policy ambitions, such as the recent European Green Deal[122]. 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.

Figure 3-7 Intermediate consumption of the EU-27 chemicals sector



Source: Ricardo analysis based on Eurostat data

3.5.2.4 Capital expenditure activity in the EU-27 chemicals sector

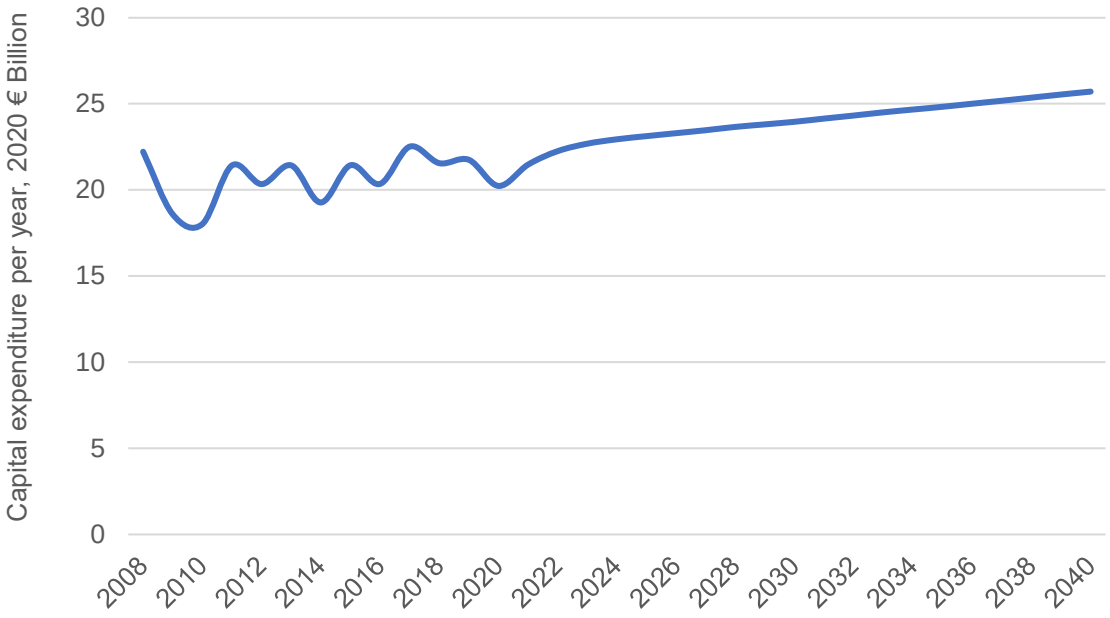
Capital expenditure by the chemicals sector has generally grown in the last decade. The investment based in the EU-27 has grown at a CAGR of 1.6% from 2009 to 2019. This growth is slower than that of China and, to a lesser extent, the North American economies. This has meant that the EU-27's share of 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%). 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.

[121] Ibid footnote 118
[122] Ibid footnote 75

Despite these limitations, 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 are shown in Figure 3-8 below.

Figure 3-8 Capital expenditure in the EU-27 chemicals sector



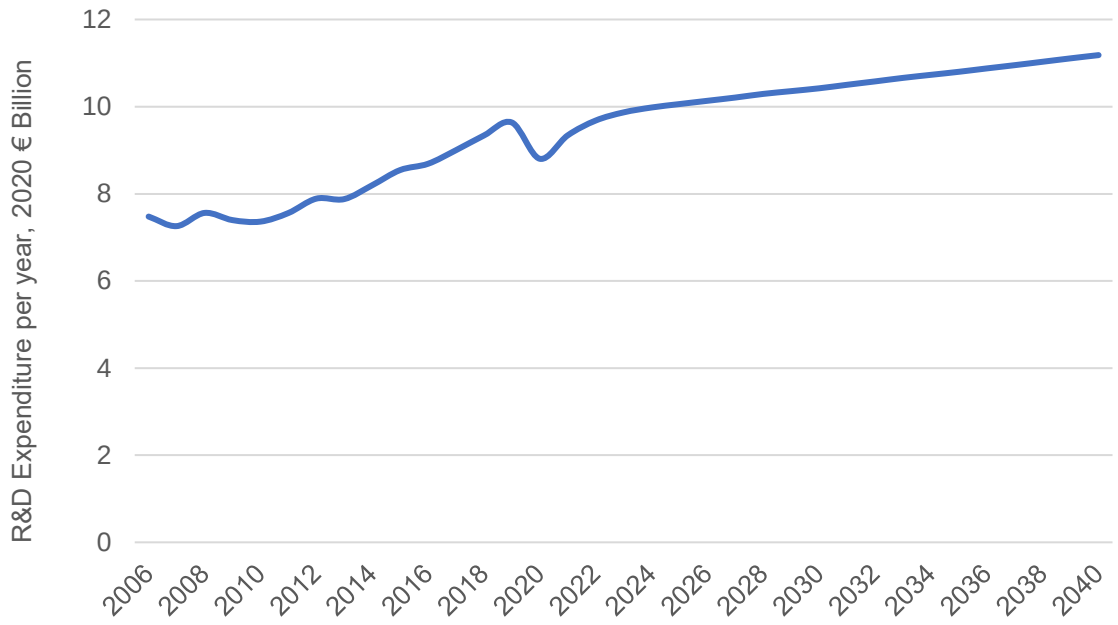
Source: Ricardo analysis based on Eurostat data

3.5.2.5 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, it is estimated that R&D expenditure will grow at least in line with the sectoral turnover, or 0.7% per year on average, as shown in Figure 3-9 below. It is possible that recent historical trends of relatively fast-paced growth will continue; however, this is uncertain.

Figure 3-9 R&D expenditure of the chemicals sector in the EU-27



Source: Ricardo analysis based on Cefic data[123]

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.

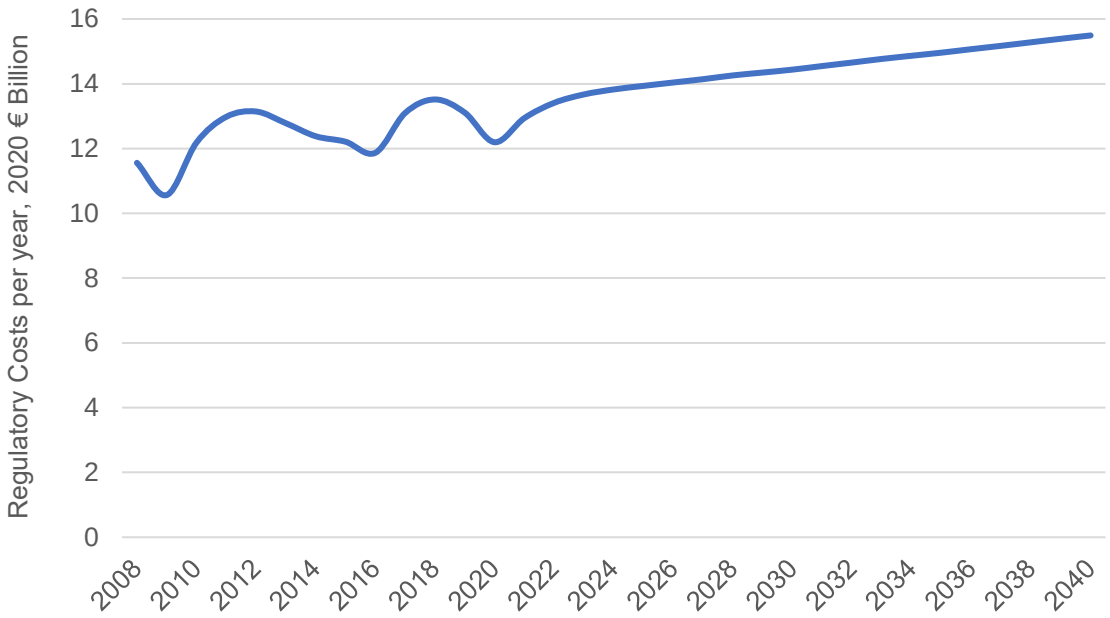
3.5.2.6 Regulatory burden of the EU-27 chemicals sector

As noted earlier, the 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU chemical industry[124] suggests that the regulatory burden affecting the sector represents over 2% of their turnover, also reported in more recent study by Cefic[125].

In the baseline scenario, it is assumed that the level of burden as a percentage of turnover will remain as estimated by this study. This would imply that annual regulatory burden in 2019 amounted to around €13 billion, and this burden would be likely to grow over time in line with the estimated increase in sectoral operations and associated turnover, as shown in Figure 3-10 below.

[123] Ibid footnote 118. Not all Cefic data used in this study is macroeconomic, historic and publicly available
[124] Ibid footnote 114.
[125] Ibid footnote 118

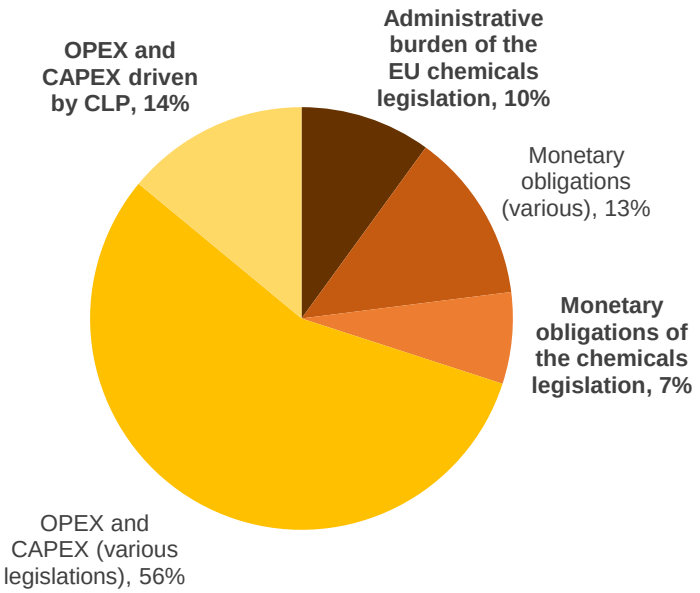
Figure 3-10 Total regulatory costs of the chemicals sector in the EU-27



Source: Ricardo analysis based on Eurostat data and Technopolis Group, VVA. (2016).

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 3-11 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 3-11 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: Technopolis Group, VVA. (2016).

Further, as an illustration of how this regulatory burden may affect the industry, a recent study by ECHA (2020)[126] 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."

3.5.2.7 Employment

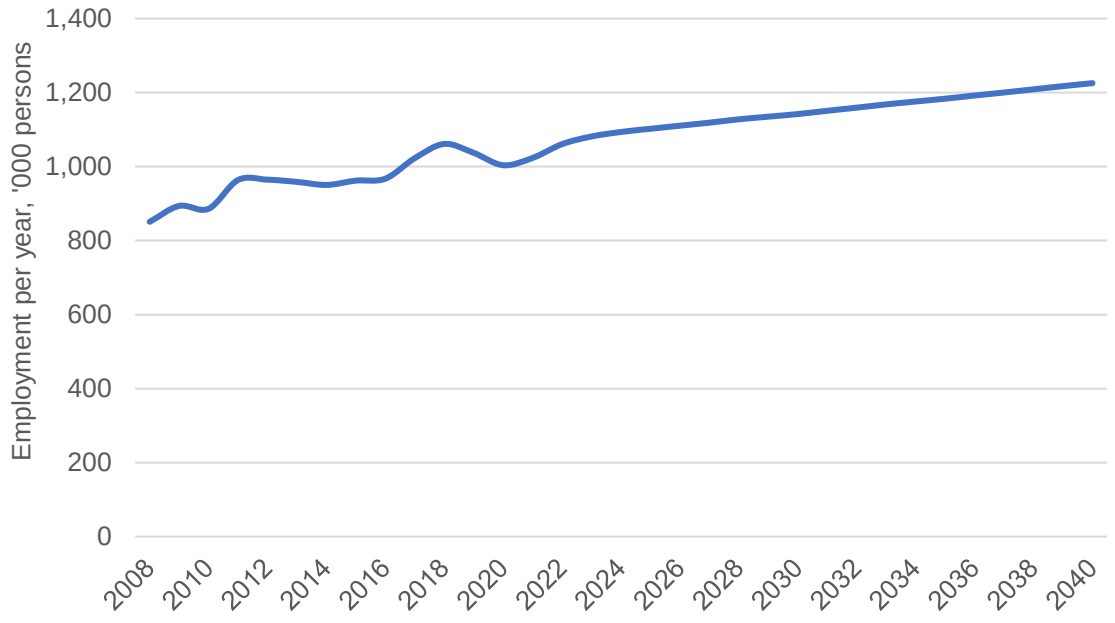
The chemicals industry is characterised by the employment of highly qualified professionals, who are remunerated accordingly. Employment compensation in the chemicals industry is among the highest, behind only petroleum refining and pharmaceuticals.

As the EU-27 chemicals sector continue 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, with the exception of a slower contraction in 2020 and a smoother recovery thereafter. This is shown below in Figure 3-12.

Figure 3-12 Employment in the EU-27 chemicals sector



Source: Ricardo analysis based on Eurostat data

[126]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 Policy options considered

This section presents the actions (short list of policy options) that are outlined in the CSS related to CLP and the extension of the GRA, as identified by the mapping and screening of the CSS actions detailed in Section 2.4, and the assumptions related to potential regulatory actions that form basis for this assessment.

4.1 Policy Options identified in the Chemicals Strategy for Sustainability

The CSS recognises the essential role of chemicals to deliver climate targets, ensure a high level of safety and holistically integrate the multiple dimensions of the Green Deal. It aims to simplify and strengthen the regulatory framework on chemicals to further increase the level of protection of human health and the environment while boosting innovation and promoting the EU's competitiveness[127]. It proposes that this is achieved by reinforcing the cornerstone legislation for regulation chemicals in the EU: the REACH and CLP Regulations, and supplementing this with a coherent approach to assessing and managing chemicals across existing sectoral legislation.

Whilst the strategy does not include detailed guidance on the proposed actions around the GRA, it does indicate the 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.

4.1.1 Addition of Hazards to the CLP Regulation

In light of the outcomes of the screening of policy options, the following shortlist have been carried forward in our analysis:

a) 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.[128]
EDs are currently categorised as "other hazards" in relevant EU legislation and their associated risks are addressed through REACH, which requires assessment of endocrine disrupting properties through substance evaluation, and allows for risk management of EDCs through categorisation as substances of very high concern (SVHC) via Equivalent Level of Concern (ELOC) criteria and as part of Restrictions.[129] However, the Commission is expected to propose to establish legally binding hazard identification for endocrine disruptors across all relevant legislation, based on the definition of the WHO and building on criteria already developed for plant protection products under the Plant Protection Product Regulation ((EC) No 1107/2009)[130] and biocides under the Biocidal Products Regulation ((EU) No. 528/2012)[131]. The objectives are to develop a common definition for sectors other than those mentioned above and standardise testing methods for identifying and classifying endocrine disrupting substances. The European Commission is expected to try to ensure that EDCs are banned in consumer products as soon as they are identified, allowing their use only where it is proven to be essential for society.

[127] The European Chemical Industry Council (Cefic). (2020). *Chemical Strategy for Sustainability*. Available from: https://cefic.org/policy-matters/chemical-safety/chemical-strategy-for-sustainability/
[128] Ibid footnote 28
[129] Ibid footnote 75
[130] Ibid footnote 65
[131] Ibid footnote 64

Furthermore, the Commission is discussing the possibility of establishing categories of endocrine disruption under the CLP in an approach akin to that taken for carcinogens, mutagens and reprotoxins (CMR)s. Under the CLP, CMRs are classified in one of the three categories:

- 1A, for substances "known" to have potential adverse effects for humans, based largely on human evidence
- 1B, for substances "presumed" to have potential adverse effects for humans, based largely on animal experimental evidence
- 2, for substances "suspected" of having potential adverse effects for humans

Rather than dividing EDCs into subcategories 1A and 1B, the Commission may create two new hazard classes of EDCs: endocrine disruption affecting human health (ED HH) and endocrine disruption affecting the environment (ED ENV).[132] However, the Commission could create a category for "suspected" endocrine disruptors, partly depending on the results of a targeted Impact Assessment that will be carried out to estimate the number of substances covered by each hazard class and category.

b) Propose new hazard classes and criteria in the CLP Regulation to fully address environmental toxicity, persistency, mobility and bioaccumulation.
Mobility will be added as an environmental endpoint, perhaps based on the criteria defined by Umweltbundesamt (UBA - German Environment Agency). Researchers in Germany and Norway have argued that persistent, mobile and toxic (PMT) substances pose a concern and should be considered hazardous substances prioritised for risk management under REACH and accounted for in chemical regulations[133].

c) Ensure that the CLP Regulation is the central piece for hazard classification and allows the Commission to initiate harmonised classifications.
The action plan more concretely indicates that in 2021 there will be a "*Proposal to amend the CLP Regulation to CLP Regulation 2021 to introduce new hazard classes on endocrine disruptors, PBTs/vPvBs and persistent and mobile substances, and apply them across all legislation"*[134]. This will entail moving PBT/vPvBs currently covered by REACH across to the CLP and creating consistency in persistence assessments across legislation. This is to ensure greater consistency in the assessment procedure of PBTs/vPvBs, as currently there are differences in the numerical criteria, evidence used for determining PBT properties, the procedures of PBT identification, and the RMMs triggered by PBT/vPvB identification across EU chemical legislation. In some cases, these differences can lead to a substance being identified as PBT/vPvB under one legislation but not another, and a PBT substance being prohibited for use in some products and applications but allowed to be used in others[135].

This may also include assessing the need for specific criteria for immunotoxicity and neurotoxicity, currently under the hazard endpoints *'Specific target organ toxicity'* and *'reproductive toxicity'* and amend them if necessary. In order to do this there would be a need to adapt existing criteria based on scientific knowledge and progress, i.e., to take account of alternative methods and clarify criteria. The need for specific criteria for immunotoxicity and neurotoxicity are being considered, with the possibility that hazard classifications will be added for both these endpoints. Currently, both of those endpoints are regulated under other classifications. This way, a level of specificity is added to the classification system. The addition of these hazard classifications would be considered as a revision to CLP, which is an EU wide revision, applicable in every single Member State and a divergence from the UN GHS. An example of a substance which is currently classified as Specific Target Organ

[132] Turley, A. (2021). Draft Commission proposal on EDCs under CLP includes 'suspected' category. [Online] Chemical Watch. Available from: https://chemicalwatch.com/234235/draft-commission-proposal-on-edcs-under-clp-includes-suspected-category
[133] Turley, A. (2020). Mobile substances are of 'equivalent concern' to PBTs, say scientists. https://chemicalwatch.com/196581/mobile-substances-are-of-equivalent-concern-to-pbts-say-scientists. [Online] *Chemical Watch*. Available from: https://chemicalwatch.com/196581/mobile-substances-are-of-equivalent-concern-to-pbts-say-scientists
[134] Ibid footnote 33
[135] Ibid footnote 36

Toxicity Repeated Exposure (STOT RE) 1 but could potentially be classified as immunotoxic or neurotoxic is aniline.

4.1.2 Extension of the GRA

In light of the outcomes of the screening of policy options, the following policy options have been carried forward in our analysis:

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 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.**
As outlined in Section 3.3.1, the generic approach to risk management is applied most commonly to CMR substances in EU chemicals legislation. This occurs in REACH Restriction under Article 68(2) and in sector specific legislation such as cosmetics, toys and food contact materials. At present the Biocidal Products Regulation (BPR) and the Plant Protection Products Regulation (PPPR) have the most comprehensive use of the GRA, prohibiting approval of active substances that are classified as CMRs, PBT/vPvB and ED for both consumer and professional use products and, in the case of biocides, prohibiting the sale of biocidal products with additional hazardous properties (acute oral, dermal and inhalation toxicity cat 1-3; developmental neurotoxic or immunotoxic).

   An extension of the GRA to other endpoints of concern is not limited to Restrictions under REACH. The Commission has put forward the proposal to extend the GRA in the Food Contact Materials Regulations to cover CMRs, PBT/vPvBs and EDs in order to meet the commitments of the Chemicals Strategy . This would however require sufficient criteria and information requirements for determining such properties of Food Contact Material (FCM) substances[136].

b) **The Commission will define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments"**
At present no definition for essential use has been decided. As such, a qualitative analysis is presented. It is expected that essential use derogations shall be incorporated into REACH Restriction process and under REACH Article 68(2) and sector specific legislation.

c) **The Commission will extend to professional users under REACH the level of protection granted to consumers.**
It is envisaged that this will entail extending the generic risk approach that is/shall be applied to consumers to professional users.

d) **The CSS indicates that those substances identified as Substances of Concern (SoC) "*are minimised and substituted as far as possible, and phasing out the most harmful ones for non-essential societal use, in particular in consumer products*."**
SoC are defined in the CSS in footnote 16 as "*These include, in the context of this strategy and related actions, primarily those related to circular economy, substances having a chronic*

[136] European Commission (2020) *Revision of EU rules on food contact materials (FCMs).* Available from: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials_en

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." Based on this, for this report a reasonable scenario has been developed for the GRA for consumers, and at a later date, for professional uses. Although not certain, this scenario assumes the changes and consequences that are likely to be triggered by the CSS.

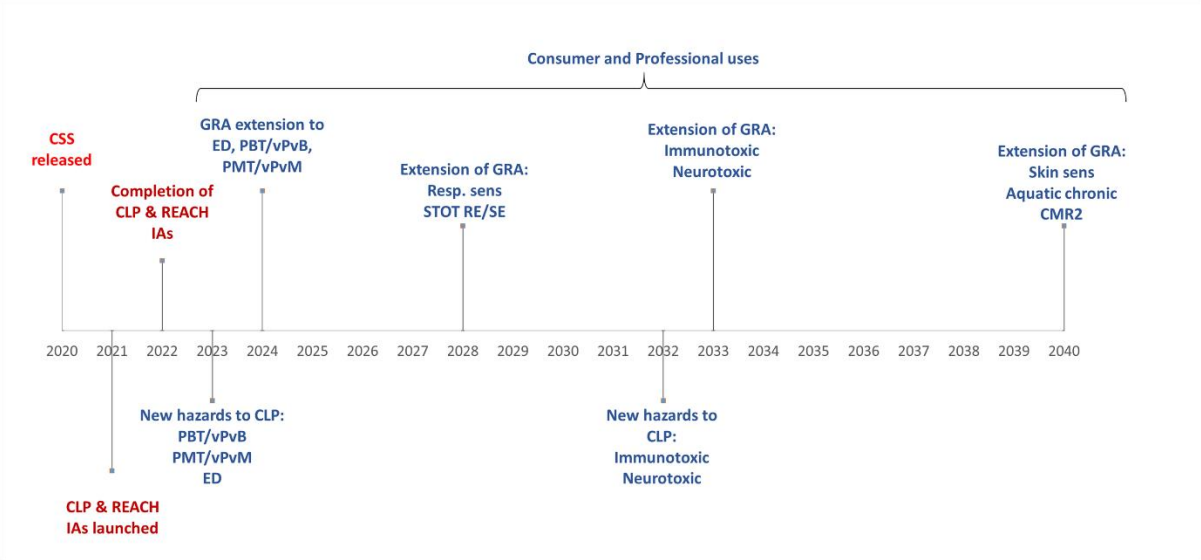
To note, potential implications of SVHC listing and subsequent Annex XIV inclusion of these substances that may apply in addition to the GRA(e.g. for industrial uses) are not included in the scope of this assessment.

4.2 Assumptions for Analysis

This section presents the assumptions that have been developed by the study team and Cefic to allow for the ex-ante assessment of business impacts. These assumptions are based on literature review of publicly available information. Two timelines are used in the analysis of impacts, one which presents a scenario where the changes to CLP and GRA are introduced within 5 years and one which presents a phased approach to implementation (see Section 5).

Figure 4-1 presents the indicative timeline for the phased implementation that has been used in our assessment of the impacts. 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 Restriction Roadmap has outlined a proposal for Restriction of skin sensitisers, in our phased implementation timeline, this has been introduced in 2040 as more hazardous classifications may take priority.

Figure 4-1 Timeline of Implementation Used in this Study



4.2.1 Assumption 1 – Substances to be Regulated

The following list of hazard classes have been identified as relevant for the Impact Assessment:

- All Carcinogenic, Mutagenic or Reprotoxic (CMR) substances, category 1A, 1B, 2
- All Endocrine disruptor (ED) substances, classified by known, possible and potential according to WHO definition.
- All Persistent, Bioaccumulative and Toxic (PBT) substances
- All very Persistent and very Bioaccumulative (vPvB) substances
- All Persistent, Mobile and Toxic (PMT) substances according to the UBA criteria.

- All very Persistent and very Mobile (VPvM) substances according to the UBA criteria.
- All Immunotoxic substances
- All Neurotoxic substances
- All Specific Target Organ Toxic (STOT) substances SE and RE category 1 and 2
- All Respiratory sensitiser substances category 1, 1A and 1B
- All Skin sensitiser substance category 1, 1A and 1B
- All Aquatic Chronic substances, categories 1, 2.

4.2.2 Assumption 2 - New hazards to CLP

The EU Chemicals Strategy for Sustainability outlines the Commission's commitment to include new hazard classes in the CLP Regulation. These hazard classes are either new (ED, PMT/vPvM), brought across from REACH (PBT/vPvB) or separated from established building blocks (immunotoxic and neurotoxic). Table 4-1 outlines the assumptions for timings of adaptation of the CLP Regulation that have been used in this assessment. These timelines have been based on the need for completion of EU Commission Impact Assessment studies, agreement on classification criteria and agreement for adoption by the European Parliament.

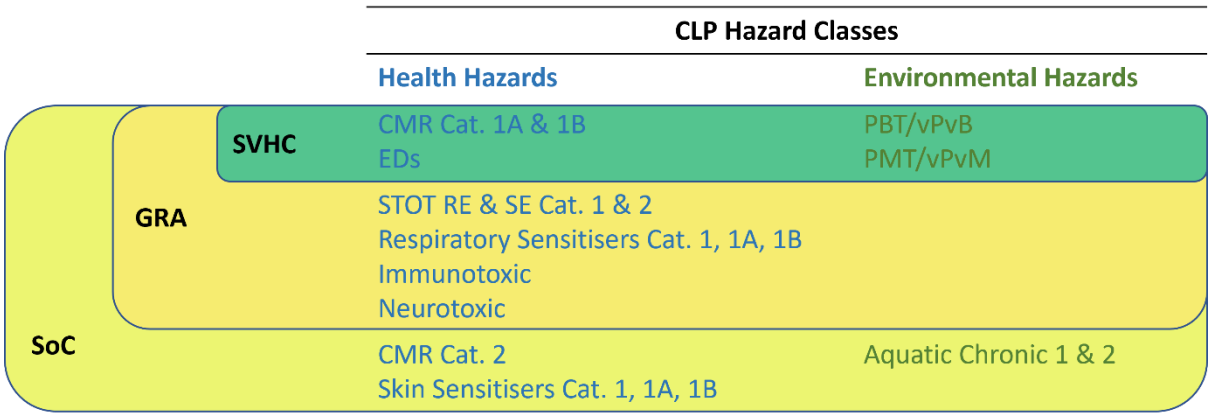
Table 4-1 Assumption 2 - Timeline for Addition of New Hazards to the CLP Regulation – assumed entry into force

Revision	Year	Hazard Class
1	2023	ED PBT/vPvB PMT/vPvM
2	2032	Immunotoxic Neurotoxic

4.2.3 Assumption 3 - Extension of the Generic Approach to Risk Management

Figure 4-2 provides an overview of the assumptions for the groups of hazard classes that could be included in the extension to the GRA. This assumption is based on expert interpretation of the CSS.

Figure 4-2 Overview of Assumed Extension of GRA



In line with the commitments outlined in the EU Chemicals Strategy for Sustainability, Article 68(2) of REACH is expected to be extended to include new hazard classes and professional users. In order for ED, PBT/vPvB, PMT/vPvM, immunotoxic and neurotoxic endpoints to be included in the extension of the GRA these hazard classifications will need to be included in the CLP Regulation. As such, it has been assumed that there would be a delay in the extension of the GRA to allow for the adaptation

of the CLP Regulation. The hazard classes deemed to be substances of very high concern (SVHCs) are also assumed to be extended to PMT, vPvM and ED substances, with EDs and PMT/vPvM no longer being considered "*equivalent level of concern*" under Article 57(f) of REACH. As outlined above, 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) are not included in the scope of this assessment.

The extension of GRA for consumer and professional-use products may not only be limited to the REACH Restriction process and REACH Article 68(2). It has been assumed that certain sector specific legislation that already utilises the GRA for certain endpoints (mostly CMR Cat 1A/1B) may also extend the GRA based on the phased approach outlined below. In reality timings may not align, but for this study, in view of the lack of more specific information, we assume the same implementation steps.

It is assumed that the extension of the GRA will take a phased approach, with SVHCs being targeted as a priority, then subsequent phases based on severity (see Table 4-2). These assumptions are based on the need for the completion of EU Commission Impact Assessment studies, adoption of new hazard classes in the CLP Regulation, revision of REACH and entry into force of implementing acts. As such, the extension of the GRA has been assumed to occur one year after the changes to CLP.

Table 4-2 Assumption 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

Whilst individual pieces of legislation may be impacted slightly differently, overall the following impacts will require certain actions as a consequence of the GRA changes. To allow for the extension of the GRA, revision of REACH and implementing acts in sector specific legislation may need to be introduced. For Regulation (EC) No 1223/2009 on cosmetic products, coherence with the existing Scientific Committee for Consumer Safety (SCCS) evaluation approaches will be critical. The 'essential use' criteria will have to be added to the list of exemption / derogation criteria in all legislation impacted.

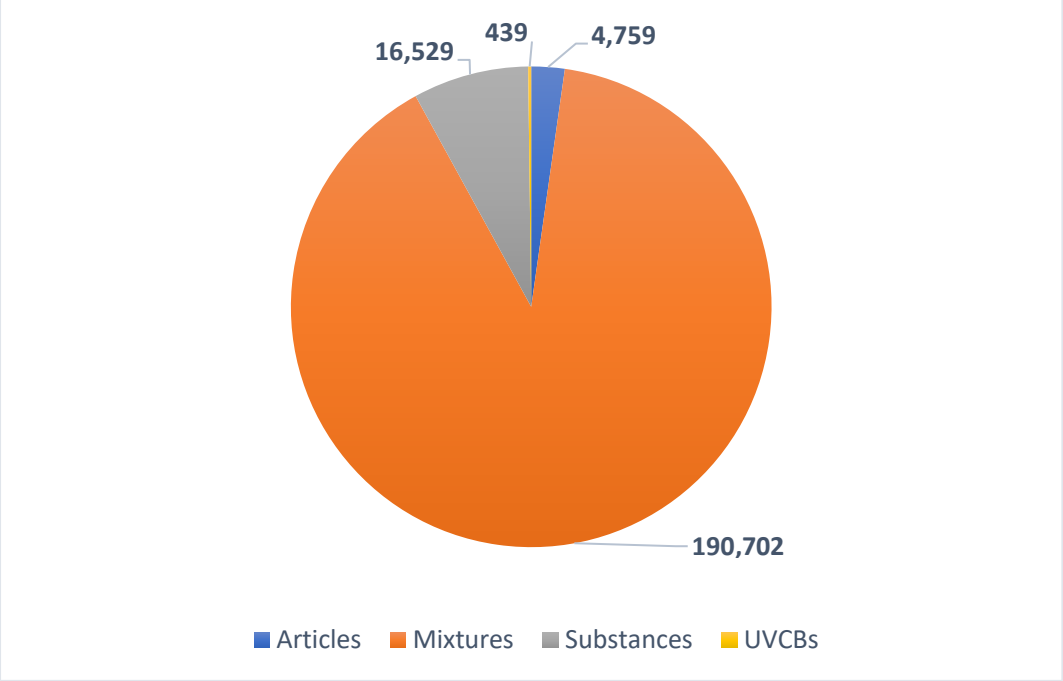
4.3 What is the scale of products that may be affected?

Whilst the scale at which products will be affected cannot be fully determined, given that the CSS does not include detailed guidance on the proposed actions, the changes as a consequence of the CSS will likely impact different pieces of legislation. Annex 1 provides an overview of the expected changes and product sectors which are most likely to be affected.

In the first consultation, respondents were asked to provide information on the products within their portfolio that contained any substances on the List of Substances to be Regulated created for this

exercise. Figure 4-3 provides an overview of the number of products per type of product (substance, mixture, article, UVCB) that may be impacted by the changes to the CLP and GRA, as reported by the consulted businesses. The majority of companies who responded to the consultation where manufacturers. These companies often sell to formulators and compounders, who in turn sell to article producers. Figure 4-3 reflects level one in the value chain. Therefore, only direct sales of respondents are considered. Data from further down the value chain was not received in this consultation, reflected by the low number of articles included (but likely indirectly covered via polymer preparations and compounds).

Figure 4-3 Number of Potentially Affected Products by Type of Product



With regard to the distribution of this potentially affected set of products by use, more than half of them were classified as Professional use products (60%), one quarter of products were classified as

Industrial use products (26%), and the remaining are considered Consumer use products (14%) (Figure 4-4).

Figure 4-4 Potentially Affected Products by Use

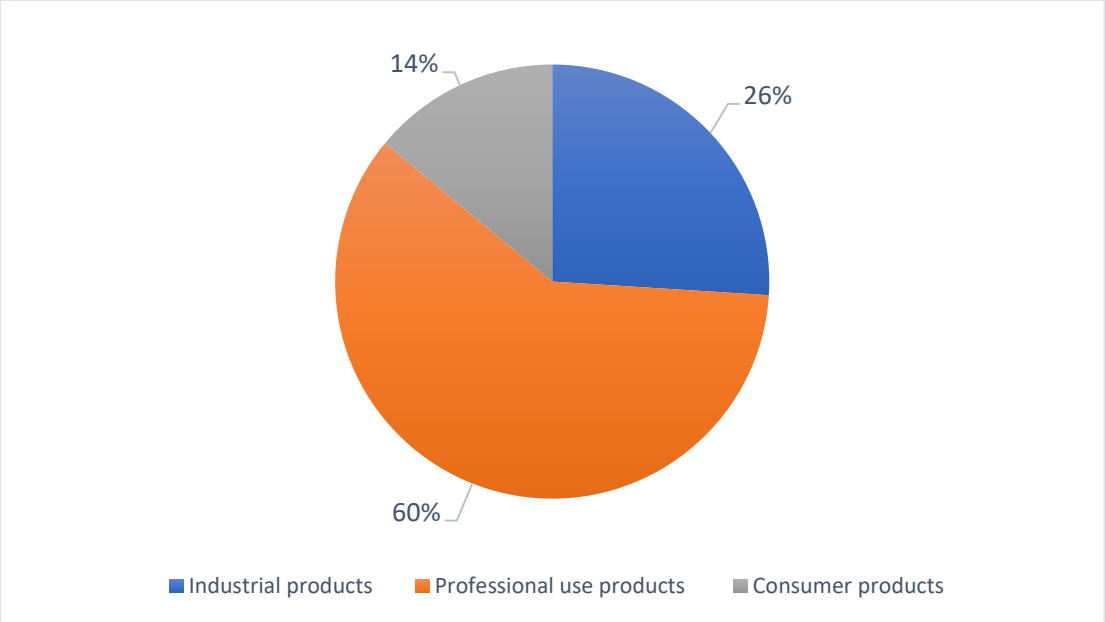


Figure 4-5, Figure 4-6 and Figure 4-7 present an overview of the sectors potentially most impacted by the changes to GRA by tonnage, turnover and number of products respectively, as indicated by the responses to the first consultation. It can be seen that the sectors, denoted by Product Category (PC) as defined in the ECHA Guidance on REACH[137], vary depending on the variable but the most significantly impacted sectors by tonnage band of products sold are:

- PC 32 - Polymer preparations and compounds;
- PC 9 - Coatings and paints, thinners, paint removers;
- PC 35 - Washing and cleaning products;
- PC 1 - Adhesives, sealants;
- PC 26 - Paper and board treatment products;
- PC 39 - Cosmetics, personal care products;
- PC 24 - Lubricants, greases, release products; and
- PC 18 - Ink and toners.

Whereas for turnover, PC 27 - Plant protection products and PC 8 - Biocidal products are among the top 10 impacted sectors, with PC 24 and PC 18 moving down. PC 8 also enters the top 10 for the number of products most significantly impacted.

Please note, some companies were unsure of the final product sector that their products were used in due to a lack of supply chain visibility. As such, respondents could select PC0 – other, or PCU – unknown end use.

[137] ECHA (2015) Guidance on Information Requirements and Chemical Safety Assessment. Chapter R12: Use Description. Available at: https://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197?t=1449153827710

Figure 4-5 Top 10 sub-sectors most impacted by the addition of hazards to CLP and the extension of the GRA: Affected Sales Volume by Sub-sector (tonnage)

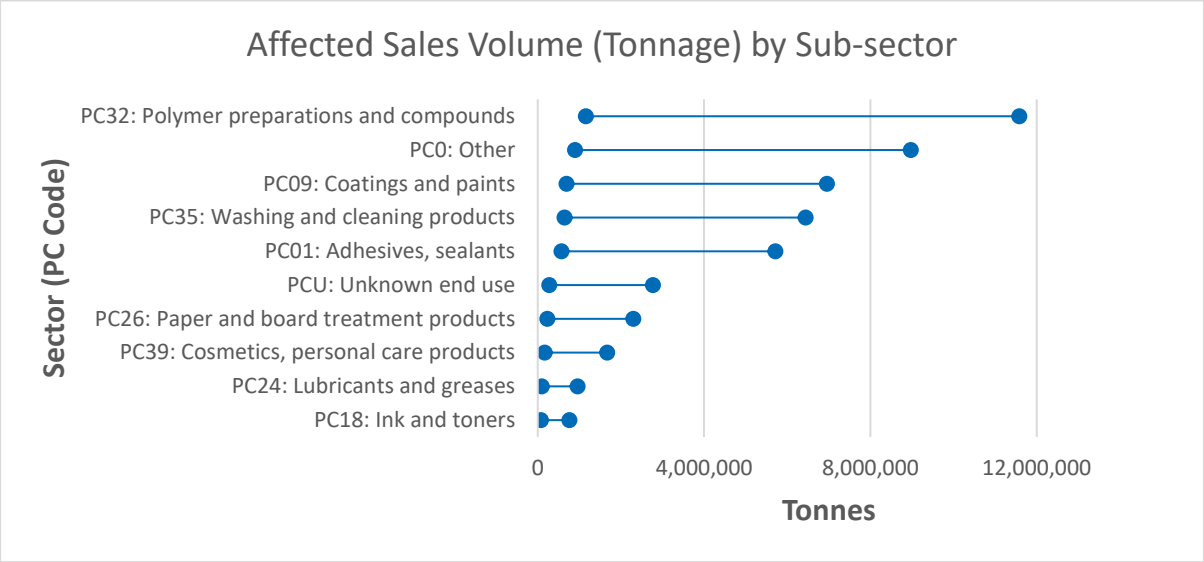


Figure 4-6 Top 10 sub-sectors most impacted by the addition of hazards to CLP and the extension of the GRA: Affected Sales Volume by Sub-sector (turnover)

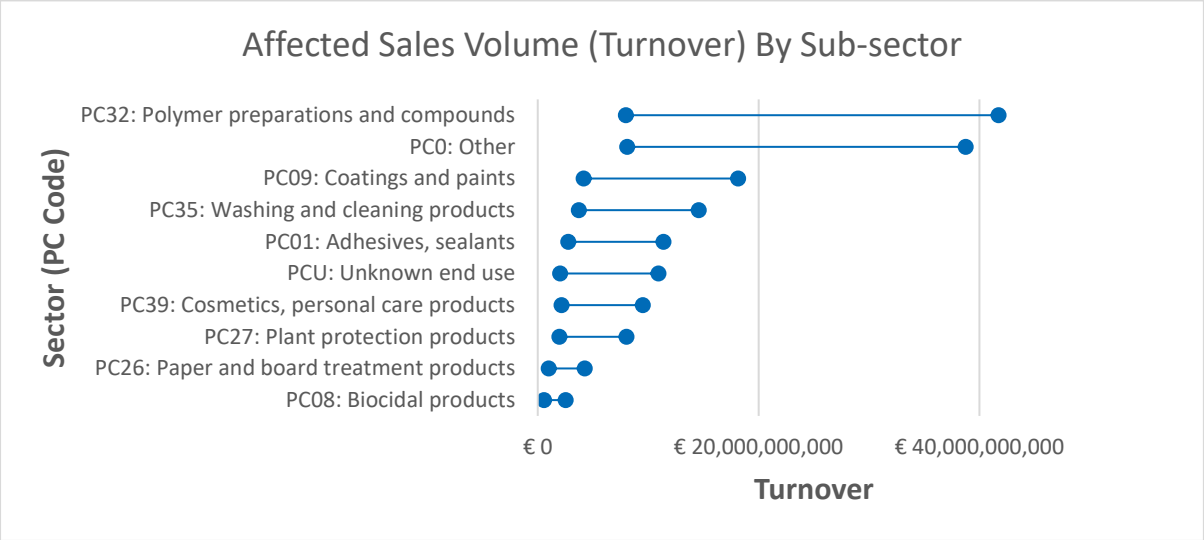
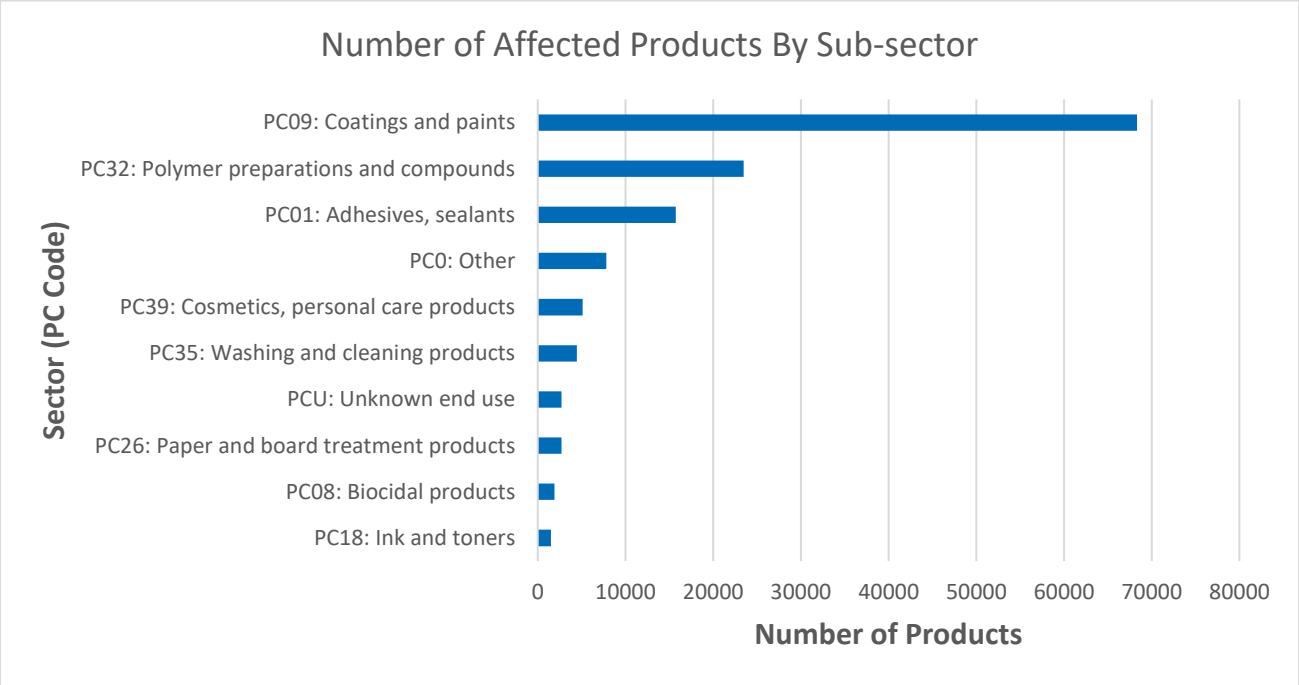


Figure 4-7 Top 10 sub-sectors most impacted by the addition of hazards to CLP and the extension of the GRA: Number of Affected Products by Sub-sector



5 Business impacts of the policy options

This section presents the ex-ante assessment of selected policy options from the proposals contained in the CSS, with a focus on how the EU-27 chemicals sector may be affected by these policies 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.

First, outputs from this assessment of potential impacts that the industry may be facing from the implementation of the policy options considered are presented. This assessment draws on the counterfactual or baseline developed in Section 3.5, the most recent available data from Eurostat, evidence gathered through the survey of over 100 participating companies and secondary research. These outputs are structured into the following sub-sections:

- The scope and potential scale of impact, as indicated by the portfolio of products that are likely to be affected by the policy options considered in this study (section 5.1.1)
- A consideration of potential business responses (section 5.1.2)
- Costs and benefits driven by the impact on the chemicals sector, including impacts on sectoral turnover and Gross Value Added; intermediate consumption and operating costs, capital investment and R&D expenditure; the regulatory burden to be faced by the sector; and employment (section 5.1.3).

Following this, a brief section (section 5.2) summarises key perspectives from the EU chemicals industry as to the potential impacts they expect from the implementation of the CSS, with a focus on the proposed changes to the GRA and CLP. This primarily draws on a survey of chemicals companies.

Finally, other business and economic impacts, especially on international trade and competitiveness, are considered more qualitatively drawing primarily on available evidence and the survey of chemicals companies (section 5.3).

5.1 Business impacts of the CLP and GRA

The changes to CLP and the GRA considered in this study are generally expected to restrict the manufacturing and use of products and/or increase their costs of production, which will in turn affect the evolution of the European chemicals market and its competitiveness.

Companies participating in the consultation were firstly consulted to identify the products they manufacture and sell that are likely to be affected by the policy options considered in this study. To do this, the participating companies reviewed all of the products that they placed on the market in the EU-27 or manufactured for export in 2019 and contained any of the substances included in the List of Substances to be Regulated. Data gathered and analysed from around 100 responses suggests that 43% of their portfolios in terms of turnover, which was equivalent to more than €240 billion of the sector's turnover in 2019, would likely be affected by changes to CLP and the GRA.

These effects would include restrictions on manufacturing and/or use of chemicals that can only be mitigated through substitution, reformulation and/or successful derogations, the latter only applying to products potentially affected by changes to the GRA.

Once the 'affected portfolio' was established, a follow-up business survey was implemented. Responses suggest that 30%-35% of the portfolio of products that would be affected, directly by restrictions or bans and indirectly by pressures for market withdrawal, could be substituted and/or reformulated, and between 5%-10% of the portfolio affected by GRA could be subject to derogations from the expected restrictions or bans.

Businesses may, therefore, be able to mitigate or alleviate less than half of the potential product withdrawals that would result from the changes to CLP and the GRA, and they would do so whilst incurring additional capital, operating and R&D expenditure.

The additional regulatory requirements facing these businesses would lead to increases in CAPEX and OPEX per unit of sales. These costs would be driven by new operating, capital and R&D expenditures associated with substitution and/or reformulation; administrative burden related to derogations from additional GRA restrictions; and other administrative and compliance costs from the addition of hazard classes to CLP and the extension of the GRA.

These impacts would, overall, affect the size and cost of operation of the EU-27 chemicals sector. In doing so, the net reduction in EU-27 business operations, or direct impacts, would propagate through the EU economy and have indirect and induced effects, estimated in terms of potential reductions in the sector's contribution to GDP and employment over time.

The outputs of this impact analysis ('implicit' analysis) are outlined in more detail in the following sub-sections, first considering the affected portfolio of products, followed by the expected business responses and the assessment of potential costs and benefits driven by these impacts on the EU chemicals sector

5.1.1 The scale of impact: the affected portfolio of products

The 'affected portfolio' reflects the products that may be in scope for bans, restrictions and/or increased regulatory requirements, directly or indirectly, as a result of the adoption of the policy options considered and provides a maximum scale of impact on the size of the operations of EU chemicals businesses.

First, the policy options considered in this assessment, that is, the changes to CLP and GRA, are described below (see also Section 4), followed by more detail and the expected timings for implementation in Table 5-1.

Changes to the CLP

New hazard classes (ED, PBT, vPvB, PMT, vPvM, Immnunotoxicants 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.

The inclusion of new hazard classes in CLP will not result in an immediate reharmonization 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 to support classification, as well as resource availability from authorities.

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, etc.). 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.

Changes to the GRA

The Generic Risk Approach 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 sector legislation. To note, the GRA does not include REACH Authorisation, it is employed via REACH Restriction (Article 68(2)) and sector specific legislation.

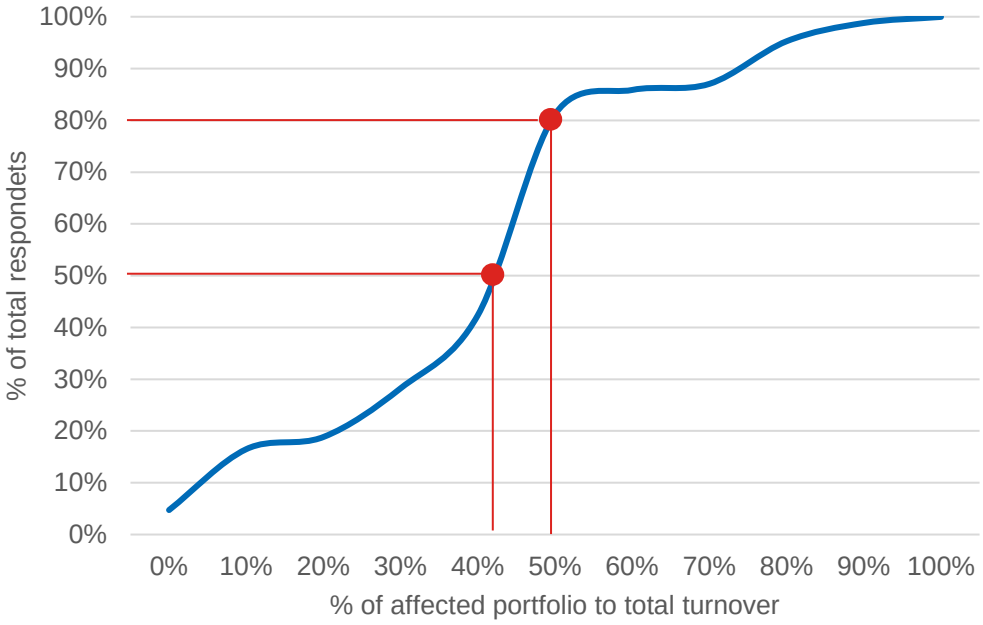
Table 5-1 Policy options considered for analysis in this study

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 hazards 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	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 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	Extend the generic risk approach to consumer and professional uses via REACH Restriction (e.g. Article 68(2)) and sector specific legislation: • ED • PBT/vPvB • PMT/vPvM	2024
		Extend the generic risk approach to consumer and professional uses via REACH Restriction (e.g. Article 68(2)) and sector specific legislation: • Resp sens. Cat. 1, 1A & 1B • STOT RE/SE Cat. 1 & 2	2028
		Extend the generic risk approach to consumer and professional uses via REACH Restriction (e.g. Article 68(2)) and sector specific legislation: • 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

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

The simple average and median percentage of the product portfolio (in terms of turnover) that may be affected by the adoption of the policy options are around 40% (39% or 43% respectively), whilst the turnover-weighted average affected portfolio is closer to 44%. The majority of respondents, or more than 80%, report that they expect less than 50% of their portfolio (in terms of turnover) to be affected. A fifth of, or 20, respondents expect a higher proportion of their portfolio being affected by the adoption of the policy options. Figure 5-1 provides a visual representation of the estimates of the potentially affected portfolio of products across survey respondents (in percent of total respondents).

Figure 5-1 Proportion of respondents and the level (%) of their product portfolio (in terms of turnover) that may be affected by the changes to GRA and CLP if implemented immediately, as assumed in this report



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

This estimate of the 'total potentially affected product portfolio' 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[138] (F1/F2) are in place. It also captures all the restrictions defined as GRA for professional or consumer use products.

Available evidence and expert opinion suggest, however, that the policy options may not be implemented immediately (i.e., in 2023) nor in full. Rather, the Commission implements specific regulatory actions over time (see Table 5-1), especially as some of the expected classification criteria remain uncertain.

Therefore, the evidence collated was overlayed with a policy implementation timeline to produce the **'total potentially affected portfolio with an assumed implementation timeline (**Table 5-1**)'**. In essence, this step distributes the reductions in EU chemicals sector's product portfolio from 2023-

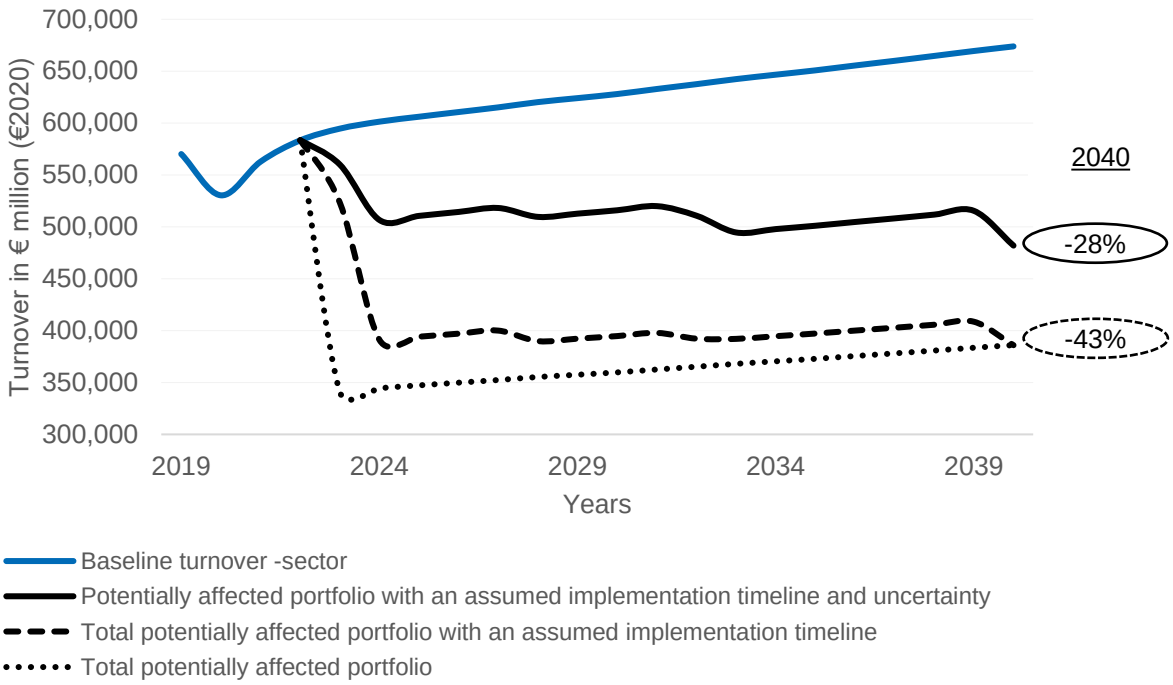
[138] CMR 1A/1B, PMT, vPvM, PBT, vPvB, ED, STOT SE/RE 1/2, Respiratory Sensitisers, Immunotox, Neurotox.

2040. No business response, e.g., substitution, is considered yet. By the end of the period of assessment (2040), the size of the products in scope of being affected by changes to the GRA and CLP remains around 43% of projected sectoral turnover.

Finally, policy uncertainties were taken into account to estimate the **'potentially affected portfolio with an assumed implementation timeline and adjustments made due to uncertainty around the classification criteria'**. Weightings were applied to the total portfolio in scope to take into account that criteria for the new hazard classifications are yet to be introduced to CLP (see Section 2.6). It is, therefore, possible that some of the 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 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 (2021). After these weightings 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.

Figure 5-2 presents the estimates of the size of the portfolio of products in scope of being affected from changes to the GRA and CLP against the baseline projections of turnover.

Figure 5-2 Product portfolio (in terms of turnover) that is in scope of being affected by the policy changes against market baseline projections



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

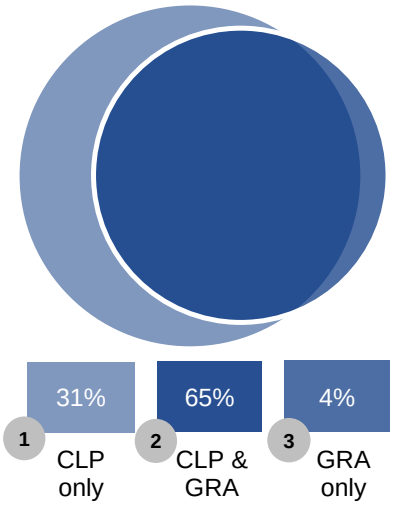
These estimates could be considered unlikely upper bounds for the potential reduction of the EU chemicals market in the event that the proposed changes to CLP and the GRA are adopted in full and the EU chemicals industry does not adapt, where possible, to mitigate these impacts. The final estimate of the 'potentially affected portfolio with an assumed implementation timeline and adjustments made due to uncertainty around the classification criteria' is considered the best estimate of the market that may be in scope of impact from changes to the CLP and the GRA. Although uncertainty remains, this final projection of the potentially affected portfolio of products is taken forward as the basis for quantifying the potential impacts on the EU chemicals sector and knock-on effects on the broader economy.

5.1.2 Expected business responses

Businesses will respond in different ways depending on the policy change that is affecting their products (i.e., GRA and/ or CLP changes).

Earlier estimates presented an overall picture of the affected portfolio. Some of these products will be affected by both changes to CLP and the GRA, whilst others will only be affected by changes to one or the other. Figure 5-3 breaks this down in terms of the percentage of the affected portfolio that is affected by changes to CLP and/or GRA.

Figure 5-3 Breakdown of the potentially affected portfolio of products by policy change in % of turnover (where 100% is equivalent to the size of the total potentially affected portfolio of products)



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

When changes to CLP and the GRA are implemented simultaneously, it is estimated that 69% of the total affected portfolio of products will be facing substance manufacturing and/or use restrictions. The rest, 31% of the portfolio that would only be potentially affected by CLP, would primarily face increased regulatory burden. Indirectly, however, it has been assumed that only a quarter of these products may face indirect pressures for market withdrawal or substitution.

The evidence collected for the study commissioned by Cefic suggests that, in response to the affected portfolio that may face direct restrictions/bans (69% of the total), businesses will substitute and/or reformulate around a third of their products to mitigate the market losses, although this will depend on a positive market uptake. Box 5-1 outlines the evidence collected related to the EU chemicals sector's capacity to substitute and/or reformulate that has been considered in this analysis.

To a lesser extent, around 5%-10% of the products affected by the changes to the GRA could also benefit from successful derogations. The requirements and processes for seeking derogations from the GRA are under development. It is expected that, where derogations do not already exist, they may be sought on the basis of disproportionate socio-economic impact and/or economic non-viability, essential use and/or other criteria to be defined.

In addition, a quarter of the products that may only be affected by changes to CLP (equivalent to 8% of the total affected portfolio) are assumed 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 potential market losses.

Box 5-1 Substitution and/or reformulation of products that may be affected by the policy options

Substitution and/or reformulation of products that may be affected by the policy options

Over 100 businesses were surveyed to gather evidence as to the extent to which they may implement specific actions resulting from the adoption of policy changes and their likely scale, especially including substitution and/or reformulation.

Businesses surveyed suggest that they **would be able to substitute and/or reformulate around 33% of the products (in terms of turnover) that may be affected** by the changes to the GRA and CLP, although there is some uncertainty.

Business expectations are affected not only by what might be technically and economically feasible but also how their customers may react to the substitutes and/or reformulated products.

The survey suggests that the ability of businesses to substitute the products that may be affected could range between 27% and 41% of their affected portfolio, on average, although this is uncertain and will depend on a positive market uptake. Further, over 60% of respondents suggest that substitution and/or reformulation would not surpass 50% of the products they place in the market. But ability of businesses to substitute and/or reformulate will be very different across business type, size and sub-sector.

Businesses may also **need time to adjust their operations and establish a final substitute and/or reformulated product that can be placed in the market**. In some cases, businesses may already have a readily marketable alternative to place in the market upon adoption of policy changes. In others, businesses may require years of research and development and product approval before an alternative can be brought to the market.

ECHA (2020)[139] presents results from a survey on the time that may be required for substitution. Their survey responses suggests that "36% of respondents may take more than seven years, (…) 20% indicated four to six years as sufficient time to complete the substitution activities, [and] 44% (…) could switch to an alternative in less than three years…".

In conclusion, some substitution and/or reformulation is likely and businesses will attempt to maximise this where economically viable; however, this is only likely to mitigate around 27%-41% of total potential market withdrawals resulting from regulatory changes and take time to implement.

Source: Ricardo analysis based on a bespoke survey of Cefic business members; and ECHA (2020). "Impacts of REACH restriction and authorisation on substitution in the EU"

The rest of the products that may only be affected by changes to CLP (equivalent to 23% of the total affected portfolio) 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 suggests that businesses 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, except for in cases where there might be strong or growing competition from players based outside of the EU.

Box 5-2 outlines the evidence collected of the EU chemicals sector's capacity to pass increased regulatory burden onto clients and the market responsiveness to potential product price changes.

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

Box 5-2 The EU chemicals sector's response to increased regulatory burden

The pass through of regulatory burden for products that may be affected by the policy options

Businesses participating in this consultation also considered the extent to which they would be able to pass through any additional regulatory burden down their supply chain, which is estimated to range between 40% and 60%.

These businesses also explored the price elasticity of their product portfolio in the EU-27. Respondents were not asked to report any information of the prices of their products, but rather their ability to pass through ay increases regulatory costs to their customers and their customers' potential responsiveness to such adjustments in prices.

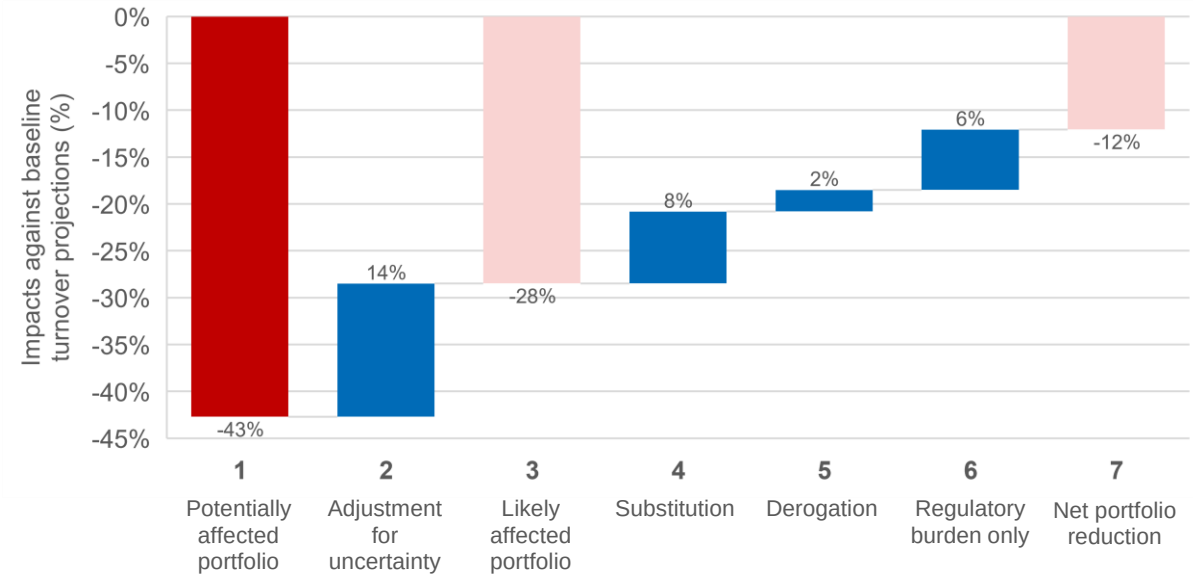
Overall, they considered that their products are, on average, price inelastic, with price elasticity of demand estimated at around -0.1. This means that the tonnes of chemicals or quantity sold in the EU-27 are not very responsive to price changes, that is, a 10% increase in chemicals prices would only result in a 1% reduction in the quantity sold.

This means that, given current market dynamics, businesses may be able to pass on a part of the increased regulatory burden to their clients with limited additional impacts on the size of their operations. This could, however, change (i.e., worsen), for example, if customer preferences vary and competition from international markets increases, which have not been considered in this study.

Source: Ricardo analysis based on a bespoke survey of Cefic business members

Finally, Figure 5-4 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 estimated to result from the introduction of the policy changes considered in this study (central estimates).

Figure 5-4 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 the 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 and/or 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 and business (in turnover terms) of around 12% or equivalent to €70 billion of the 2019 market (**Step 7**).

The following section delves into the net impacts of the policy options on the EU chemicals sector across a number of business and economic indicators, explores the sensitivity of some of the key assumptions employed in the analysis, and considers the core limitations.

5.1.3 Costs and benefits driven by the impact on EU Chemicals businesses

The consultations with chemical companies enabled the confirmation of the scope of the portfolio that is likely to be affected by the proposed changes to the GRA and CLP and the identification of potential business responses.

To 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[140]. This baseline scenario assumes that CSS is not implemented, GRA is not extended, and CLP remains unchanged.
- A first policy scenario (**Scenario 1**) considers the addition of hazard classes to CLP and extension of the GRA over a gradual implementation timetable (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 is estimated to be relatively small.
- A second scenario (**Scenario 2**) assumes a faster, 5-year implementation timetable of the expected changes to the GRA and CLP (instead of the 15-year timetable considered in Scenario 1). 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.
- A third scenario (**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[141], 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, turnover will converge to the levels estimated in earlier scenarios.

[140] Eurostat (2021), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 09/2021

[141] 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

Based on these policy scenarios and the available evidence from the bespoke business consultations, Eurostat and secondary research, the net impacts on the EU-27 chemicals sector and the knock-on effects on the EU-27 economy were assessed against the baseline scenarios. These are described in eight sub-sections:

- Turnover
- Gross Value Added
- Intermediate consumption and operating costs
- Capital expenditure
- Research and Development
- Regulatory burden
- Employment
- SME versus large enterprises

5.1.3.1 Turnover

The adoption of the policy options considered is estimated to lead to a reduction in sales or size of the EU Chemicals sector in terms of turnover[142] and tonnes manufactured and sold. 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.

First order effects, that is, the impacts on business operations excluding any pass through of additional regulatory costs to customers through price adjustments, are considered in Table 5-2.

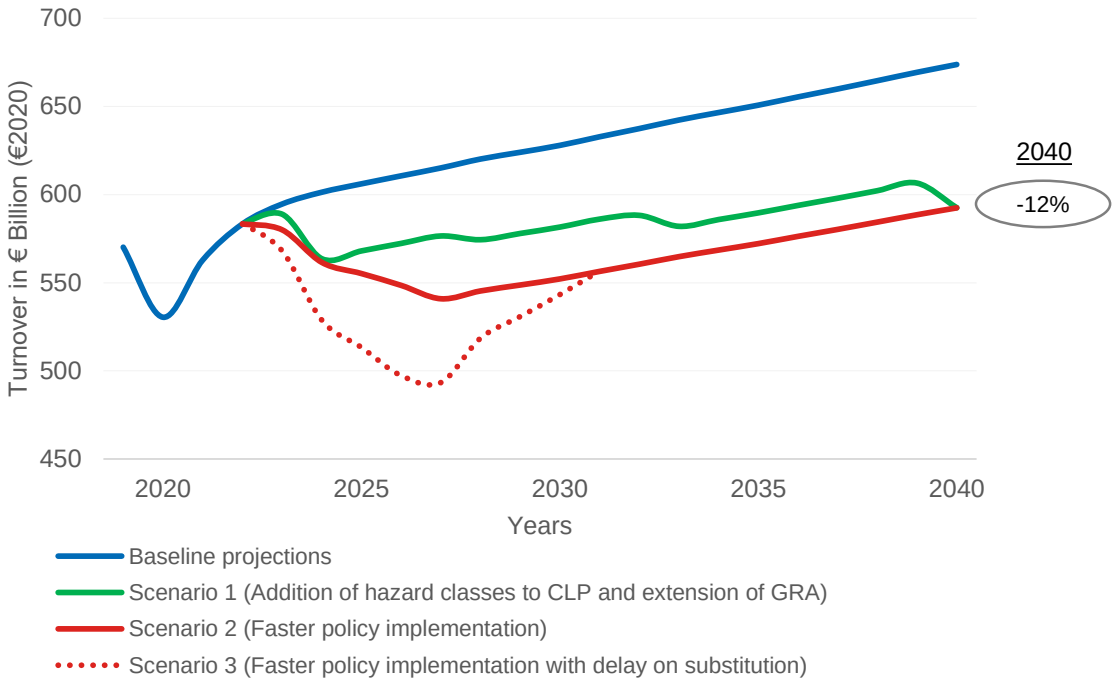
Table 5-2 Annualised impacts on the size of the EU chemicals sector against the baseline scenario in terms of turnover (€ 2020)

Scenario	First order effects or impacts on businesses overall
Scenario 1 (Addition of hazard classes to CLP and extension of the GRA)	The EU Chemicals sector is estimated to **lose €47 billion (€2020) of turnover each year on average** over the period 2023-2040, when compared to the baseline scenario.
Scenario 2 (Faster, 5-year implementation timetable)	The EU Chemicals sector is estimated to **lose €67 billion (€2020) of turnover each year on average** over the period 2023-2040, when compared to the baseline scenario.
Scenario 3 (Faster implementation timetable with delay on substitution/ reformulation)	The EU Chemicals sector is estimated to **lose €81 billion (€2020) of turnover each year on average** over the period 2023-2040, when compared to the baseline scenario.

The impacts are also presented over time in the Figure below.

[142] Turnover refers to total sales of the EU chemicals sector, thus including sales of products in the EU or abroad. There is an implicit assumption that activities targeting export markets will also be affected, on average, in a similar way to the market targeting EU customers. The effects on the exports are uncertain and could be more or less significant than the impacts that may apply to the manufacturing and/or use of substances within or for customers in the EU.

Figure 5-5 Estimated impacts on the turnover of the EU chemicals sector against the baseline scenario (€ 2020)[143]



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.

These first-order effects (as shown in Figure 5-5) reflect the direct business response to the proposed legislative changes –by 2040, the EU chemicals market would be around 12% lower than the estimated baseline, which is equivalent to a turnover loss of around €80 billion against the baseline. These effects exclude whether companies might pass the additional regulatory burden through to their customers and the associated implications, which we refer to as 'second-order effects'.

These second-order effects have been considered based on the evidence gathered through the survey to chemical companies. Overall, based on the data available, it is estimated that companies would pass through around 60% of the additional regulatory burden resulting from the legislative changes and given that, as reported by survey participants, chemical products appear to be price inelastic, this would mitigate the estimated reduction in turnover albeit marginally (by around 1 or 2 percentage points).

Overall, this suggests that **even if businesses were to introduce mitigation measures whilst incurring additional operating and capital costs (first order effects) and they were able to pass through some of these costs to their customers (second order effects), their operations and associated economic footprint would still be likely to reduce significantly, with annual turnover losses against the baseline estimated to range from €47 billion to €81 billion per year, on average[144], between 2023 and 2040.**

The scenarios established for estimating the potential policy impacts on the turnover of the EU Chemicals sector already present the implications of key uncertainties around:

- the timetable for policy implementation (Scenario 1 vs Scenario 2 and 3)

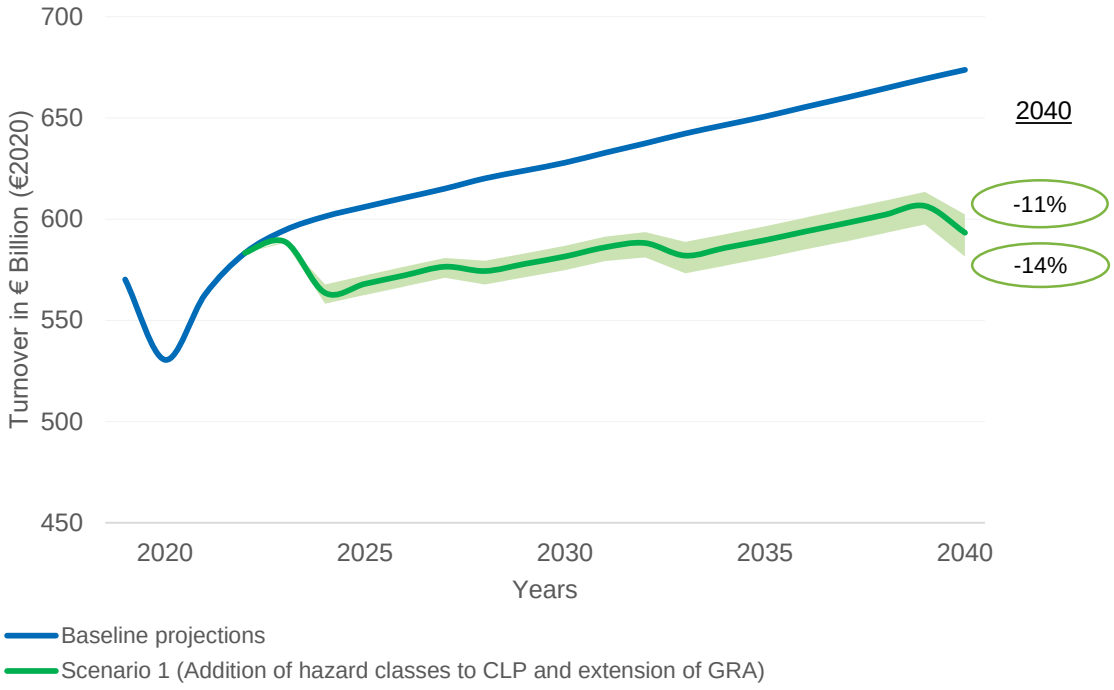
[143] Please note that the diagrammatical illustrations in this study smooth the changes in turnover over time, thus assuming that these changes are continuous (rather than discrete reductions in business). For example, in Scenario 1, it is implicitly assumed that the impact of a policy change is felt immediately and businesses start to adjust their operations slightly in advance as a way of preparing for the year in which the legislation comes into effect. In reality, businesses may take action much earlier or have a 'grace period' during which they can adjust their operations and meet the new legal requirements.
[144] A net present value of turnover losses against the baseline has been calculated, and later annualised over the period to estimate 'equivalent annual losses of turnover' as a result of the legislative changes. A real discount rate of 4% has been employed in line with the European Commission's Better Regulation Guidelines.

- the time required for businesses to adjust their operations and place substitutes and/or reformulated products in the market (Scenario 2 vs Scenario 3)

Within each of these scenarios there are other assumptions, and hence uncertainties, which could affect these estimations. In particular, the sensitivity of the results to the extent to which businesses may be able to substitute and/or reformulate has been explored.

As noted earlier in this section, if businesses do not substitute and/or reformulate at all, the EU Chemicals sector could lose 20% of the turnover estimated in the baseline (which is almost twice as much as the central estimate). The best available evidence, however, suggests that businesses will be able to substitute and/or reformulate between 27% and 41% of their product portfolios (in terms of turnover). In any of these cases, turnover losses are not estimated to vary significantly from the central estimate. This is illustrated in Figure 5-6 below.

Figure 5-6 Illustration of the sensitivity of the estimated impacts on the turnover of the EU chemicals sector against the baseline scenario (€ 2020) to expected substitution and/or reformulation



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.

Moreover, substitution and reformulation could affect the quality and attractiveness of the substances and/or products sold by the EU chemicals sector. This could have additional indirect impacts on the EU chemicals market, potentially limiting the ability of businesses to reduce turnover losses especially in the face of international competition.

In addition, the estimated turnover losses assume that the sector's capacity to pass through the higher regulatory costs remains relatively unchanged, whereas this need not be the case in the face of growing international competition, especially in the export market. If international competition increases, it would do so to the detriment of the EU chemical companies, which would lead to worse potential turnover losses (against a baseline) in any given scenario. It has not been possible to quantify this effect in this study.

Further, there are some products that are not affected directly by changes in the GRA, but they are, however, potentially affected by changes to the CLP. For these products, it has been assumed, based on expert input, that around a quarter may suffer increased pressure for market withdrawal or substitution and reformulation. This assumption is impactful albeit unlikely to affect the results significantly, as the portfolio of products that is affected by changes to CLP and not GRA is proportionately small.

Finally, sectoral economic output is assumed to be affected by the same proportion as turnover. GVA, however, depends on impacts not only on turnover and output, but also on intermediate consumption (or operating minus employment costs). This is considered in the next section.

5.1.3.2 Gross Value Added (GVA)

The adoption of the policy options considered will also lead to reductions in sectoral GVA. These reductions will, however, be lower in magnitude to that of turnover or output, although this would depend on the ability of the EU-27 chemicals industry to pass on to their customers some of the increases in regulatory burden.

GVA is affected by changes in output, or turnover, and intermediate consumption. The policy options are likely to result in decreases in turnover and increases in intermediate consumption, both drivers leading to reductions in GVA. This impact in GVA would represent first order effects. However, as noted earlier, businesses have the ability to pass through some of these additional regulatory costs or burden to their customers. These second order effects would partially alleviate the reductions in turnover and, as a result, mitigate first order impact or reduction in GVA.

Table 5-3 below outlines the estimated impacts on GVA of the EU chemicals industry, accounting for the ability of businesses to pass through additional regulatory burden onto their consumers for three scenarios.

Table 5-3 Estimated impacts on the GVA of the EU chemicals sector against the baseline scenario (€ 2019)

Scenario	Direct impacts on sectoral GVA
Scenario 1 (Addition of hazard classes to CLP and extension of the GRA)	The EU Chemicals sector is estimated to **lose €13 billion (€2020) of Gross Value Added each year on average** over the period 2023-2040, when compared to the baseline scenario.
Scenario 2 (Faster, 5-year implementation timetable)	Overall, in this scenario, the EU Chemicals sector is estimated to **lose €19 billion (€2020) of Gross Value Added each year on average** over the period 2023-2040, when compared to the baseline scenario.
Scenario 3 (Faster implementation timetable with delay on substitution/ reformulation)	Overall, in this scenario, the EU Chemicals sector is estimated to **lose €23 billion (€2020) of Gross Value Added each year on average** over the period 2023-2040, when compared to the baseline scenario.

That is, the analysis suggests that **the sector's GVA would lose between €13 billion and €23 billion each year on average over the period 2023 and 2040, when compared to the baseline scenario.** These effects are considered direct, in that they reflect the impact on the EU chemicals sector only. Such effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EU economy (induced effects), leading to even larger reductions in the sector's contribution to GDP.

Total impacts on the economy: The direct, indirect and induced effects

The decrease in the GVA of the EU chemicals sector is likely to have knock-on effects on the sector's supply chain (indirect or Type I effects). The direct and indirect effects are also expected to translate into a reduction in employment and thus overall compensation, which would in turn further reduce consumption and have broader implications across the economy (induced or Type II effects).

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the policy options on the EU chemicals sector have been estimated using an Input-Output methodology. The cumulative Type I and Type II multipliers have been assumed at around 2.8 and 3.4 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

Based on this, **total reductions in GVA driven by the effects of the policies considered on the EU chemicals sector could range between €40 billion and €68 billion every year on average between 2023 and 2040, which would be equivalent to shaving between 0.3 to 0.5 percentage points off the EU-27 GDP.**

Source: Ricardo analysis based on Eurostat data and a bespoke survey of Cefic and partner associations members

5.1.3.3 Intermediate consumption and operating costs

More than 60% of the chemical companies surveyed for this study confirmed that they would require to change their operations and manufacturing processes as a result of these policy changes.

First, the withdrawal of products from the market would necessarily imply that chemical companies would reduce their operating activities and, as a result, operating expenditure will fall. This reduction is likely to be proportional to turnover losses against the baseline. As an illustration, a reduction in business operations of around 10% would result in reduction in operating costs over time. For example, in 2019, an operational contraction of 10% would have been equivalent to a reduction in intermediate consumption of around €40 billion.

Secondly, companies would also take action to find alternatives and/or substitutes to alleviate the estimated reduction in their business. Thus, some of the current operations would need to be adjusted for the manufacturing and placing in the market of substitutes and/or reformulated products. Further, additional administrative and compliance requirements, such as seeking derogations and/or adjusting the labelling of products, and associated costs would also be incurred. As an illustration, estimates based on the survey to chemicals companies suggest that an additional €3 billion of recurring costs could be incurred as a result of substitution, reformulation, derogations and labelling and other CLP-related activities.

Overall, intermediate consumption and operating costs are likely to fall. These net reductions on intermediate consumption and OPEX would be driven by the significant losses that are estimated to the size or operations of the EU chemicals market. These estimates do not suggest, however, that there will be any cost savings from the adoption of the legislative changes. In fact, unit costs are estimated to increase. For example, the 'ratio of intermediate consumption to turnover' is likely to increase by up to 3% in 2040 against the baseline.

5.1.3.4 Capital and R&D expenditure

Similarly, the withdrawal of products from the market would have some implications on the capital and R&D expenditure by chemical companies. If the size of their business declines, it is assumed that their overall expenditure will decline as well. As an illustration, a 11% reduction in the size of chemical companies in the EU may lead to an eventual reduction in overall investment of similar proportion, which would be equivalent to reducing investment by over €35 billion in 18 years (with a net present value of over €20 billion) or around €2 billion each year against the baseline.

Nevertheless, these companies will also need to increase their investment in capital and R&D as they work to, for example, change their manufacturing processes, identify quality substitutes and alternatives and reformulate products. Based on the survey of chemical companies, it is estimated that an additional €6 billion (€2020) would be invested over 10-15 years from the adoption of the policy changes to support these changes that chemical companies would need to embark on to mitigate further operational and turnover losses.

Overall, net reductions on intermediate CAPEX and R&D expenditure are estimated, but they could be more significant in the absence of the investments in capital and R&D that are required to attain the desired substitution of substances subject to restrictions. As an illustration, the CAPEX or R&D expenditure associated with products that would be withdrawn due to policy changes is unlikely to be

maintained in the EU. Studies of the impact of REACH, such as CSES (2012)[145], also highlight the likely negative effects from having to meet new compliance requirements and this leading to some reallocation of resources. Over 40% of respondents to a survey carried out for this CSES study suggested that impacts would be negative and even more thought that these effects would worsen in the future.

These reductions in expenditure do not mean that there will be any cost savings from the adoption of the legislative changes. In fact, unit expenditure could increase, at least with regards to adjusting manufacturing processes and completing the required investments for effective substitution and reformulation. Based on the survey of chemical companies for this study, the 'ratio of CAPEX to turnover' is estimated to increase against the baseline by between 2%-5% on average, over the period 2023-2040.

5.1.3.5 Regulatory Burden

Regulatory burden refers to all of the administrative and compliance costs that result from EU legislation. This includes direct administration costs (e.g., sharing information, engaging with administrative process and associated charges, etc.) as well as compliance costs, including OPEX and CAPEX, associated with the response to any regulatory change (e.g., changes to manufacturing or products that incur both operating as well as capital expenses).

The Cumulative Cost Assessment (2016) estimated a regulatory burden affecting the EU chemical sector of over 2% of turnover. This estimate was used to develop a baseline against which to assess potential impacts. The survey of chemical companies carried out for this study also confirmed that regulatory costs are likely to be between 1%-10% of the turnover.

As a result of the adoption of changes to the GRA and CLP, **regulatory burden is likely to increase against the baseline from 2% to up to 3% of turnover, which is equivalent an additional €0.5 billion in regulatory burden per year on average over the period 2023-2040.**

Further, as noted earlier, changes to the GRA and CLP would also lead to potential turnover or operational losses. If these impacts were considered direct opportunity costs of the regulatory changes, it would imply that actual or effective regulatory burden would be significantly higher and likely equivalent to around 15% of turnover by 2040, when compared to the baseline.

5.1.3.6 Employment

The adoption of the policy options considered in this study is estimated to lead to a direct net reduction in the jobs supported by the chemicals sector in the EU-27. This reduction is primarily driven by the potential reduction in size of the chemicals sector that is estimated to result from the adoption of changes to the GRA and CLP.

The scale of impact on employment is estimated to be lower than the impact on turnover. This has been established by reviewing historical trends and confirmed by businesses participating in a survey for this study. This is partly driven by the need to retain employees to meet any additional regulatory requirements and the rigidity of the labour market, among others.

For example, evidence on the impacts of REACH, e.g. CSES et al (2015)[146], suggests that additional compliance cost led to increased labour requirements in the chemicals sector, not only due to needing additional staff but also the due to additional remuneration, skills, training and/or retraining costs.

In this context, it is estimated that, by the end of 2040, over 40,000 jobs would be lost against the baseline scenario, which is equivalent to 3% of the chemicals sector's workforce. These direct job losses would be even larger if the chemicals sector were unable to substitute and/or reformulate as noted in their survey responses, which will inevitably depend on a positive market

[145] CSES (2012). *Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry*. Available from: https://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study5.pdf
[146] CSES et al (2015). *Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs*. Available from: monitoring-the-impacts-of-reach.pdf

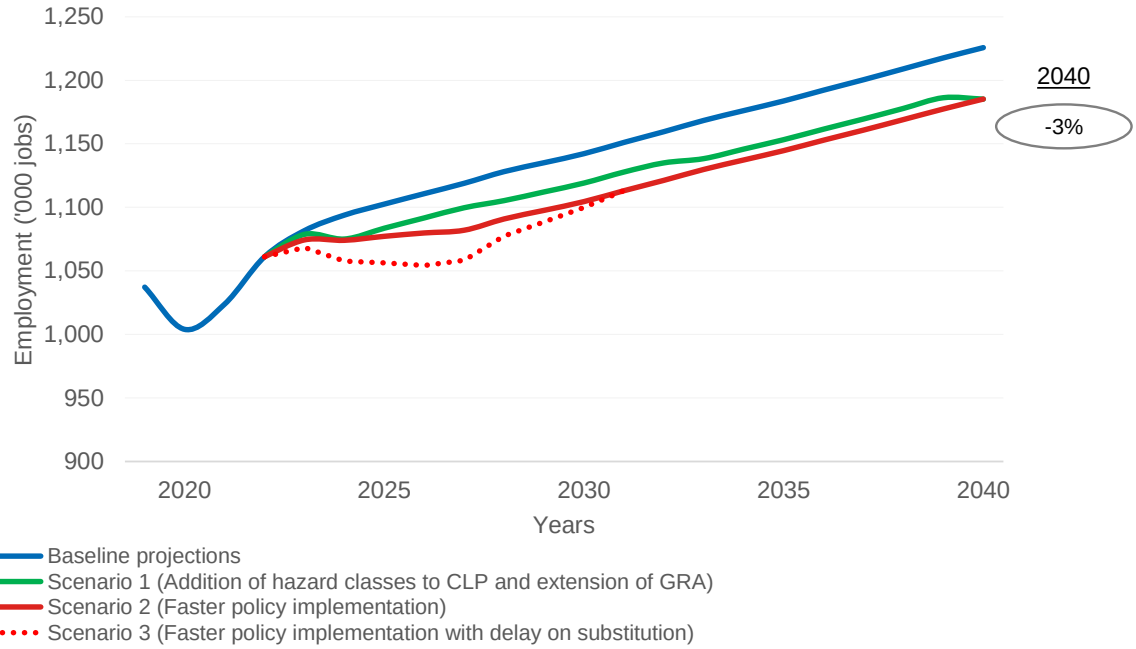
response to the substituted and/or reformulated products. Table 5-4 below describes the estimated average impacts on the sector's employment in three scenarios.

Table 5-4 Estimated average impacts on the employment of the EU chemicals sector against the baseline scenario (jobs)

Scenario	Estimated average impacts on employment in the sector
Scenario 1 (Addition of hazard classes to CLP and extension of the GRA)	In any given year over the period 2023-2040, EU Chemicals sector is estimated to employ 25,000 fewer workers on average, when compared to the baseline scenario.
Scenario 2 (Faster, 5-year implementation timetable)	In any given year over the period 2023-2040, EU Chemicals sector is estimated to employ 34,000 fewer workers on average, when compared to the baseline scenario.
Scenario 3 (Faster implementation timetable with delay on substitution/ reformulation)	In any given year over the period 2023-2040, EU Chemicals sector is estimated to employ 41,000 fewer workers on average, when compared to the baseline scenario.

These impacts on employment in the sector are also presented in the Figure below.

Figure 5-7 Estimated annual impacts on employment in the EU chemicals sector



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

As noted, the analysis suggests that the EU chemicals sector's employment would likely be 3% lower by 2040, equivalent to losing over 40,000 jobs against a baseline. These effects are considered direct, in that they reflect the impact on the EU chemicals sector only. Such effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EU economy (induced effects), leading to even larger reductions in the sector's contribution to employment.

Total impacts on employment: The direct, indirect and induced effects

The decrease in employment in the EU chemicals sector is likely to have knock-on effects across the supply chain (indirect or Type I effects). These direct and indirect effects are also expected to

translate into changes on overall compensation and, thus, disposable income, which would in turn further reduce consumption and have broader implications in the economy (induced or Type II effects).

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the policy options on the EU chemicals sector have been estimated using an Input-Output methodology. The cumulative Type I and Type II multipliers have been assumed at around 2.1 and 3.1 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

Based on this, **the adoption of changes to GRA and CLP could lead to a reduction of over 124,000 jobs by 2040 when compared against the baseline, which would be equivalent to shaving up to 0.1 percentage points off total employment in the EU-27**.

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

5.1.3.7 SME versus large enterprises

Whilst the evidence employed to assess impacts is deemed broadly representative of the EU chemicals industry, the sample comprises a disproportionate number of large firms. This is not deemed to be an issue for estimating the average impacts on the sector, especially since around 70% of the sectoral output is generated by large firms[147]. However, the sample breakdown and any outputs considered by firm size will need to be treated as indicative or anecdotal only.

The survey of chemical companies suggests that SMEs are more likely to find a substitute for their products. This could be driven by the type of products manufactured and/or used by SMEs, either in general and/or anecdotally by the small sample of SME respondents that participated in the survey. In this case, SMEs would expect fewer products withdrawn from the market and, therefore, a lower reduction in their operations against the baseline than larger businesses, unless substitution becomes economically non-viable or international competition grows to the detriment of businesses in the EU.

SME survey participants expected a relatively higher regulatory burden affecting their cost base, when compared to larger companies. However, when asked about specific costs that would be incurred as a result of regulatory changes, e.g., costs of substitution and reformulation, they reported lower unit costs when compared to larger firms.

This result is broadly aligned with previous assessments of the impact of existing chemicals legislation. For example, CSES et al (2015) highlight concerns about the increases in regulatory burden due to REACH, which may force smaller firms out of the market, or inhibit entry of new ones, and reduce the overall supplier base of the industry. The study also suggests that, given that SMEs are innovative, such an impact could have long-lasting negative effects on the EU chemicals sector.

The evidence collected for this study from SMEs does not appear to be sufficient to reach robust conclusions as to the differences in impact that may be expected from changes to the CLP and GRA. Evidence of impacts from existing legislation suggest that SMEs may suffer disproportionately from the effects of any additional legislation. However, further analysis and exploration would be required to ascertain how SMEs, more generally, may be affected by the policy options considered in this study.

5.2 Perspectives from the EU chemicals industry

More than 100 businesses from the EU chemicals sector were also consulted directly, primarily through a survey, on their expectations as to how they might be affected by the policy options considered. Responses are generally aligned with the outputs of the analysis carried out for this study, in direction but not in magnitude.

Chemical companies surveyed for this study expect their manufacturing output, sales and turnover to decline significantly during the decade after the adoption of changes to the GRA and CLP. Their

[147] Ibid footnote 48

expectations, as reported, would suggest that these policy changes could lead to reductions in their EU product portfolio that could range between 27% and 48%, with a central estimate of around 37%. This level of estimated turnover loss aligns with the total potentially affected portfolio of products. However, businesses also reported their ability to substitute and/or reformulate around a third of their affected portfolio, where required, which would mitigate some of these losses.

It is assumed that this expectation from businesses participating in the survey does not take into account their ability to substitute and/or reformulate products, seek derogations, or any other actions to mitigate the impacts of the legislative proposals, where possible and required. Estimating these overall impacts across key economic and business indicators is also a complex exercise. Therefore, the magnitude of the impacts that are elicited from businesses explicitly are only used as a reference or check to the outputs of the more implicit analysis carried out in this study.

The chemical companies surveyed also considered that their operating costs are likely to increase for the operations that are retained, that is, after adjusting their business due to the restrictions that cannot be addressed through substitution, reformulation and/or derogations. Businesses surveyed also expect total CAPEX and R&D expenditure to decline when compared to the baseline, but with a lower magnitude, that is, less so than the reductions in size of their operations. This means that the retained business will spend more in 'capital and R&D per unit of turnover' after the adoption of the legislative proposals than before.

Therefore, it follows that the surveyed businesses also anticipate a relevant increase in the regulatory burden they will likely face in the EU-27, which is again aligned with general expectations and the analysis carried out for this study.

Finally, businesses surveyed also expect a reduction in employment albeit lower in magnitude than output, as might be expected from rigidities of the labour market in the EU, delays in adjustments and the additional needs to employ people to manage additional regulatory requirements and implement any transformation or changes to their manufacturing and other activities.

Estimating these overall impacts across key economic and business indicators is a complex exercise. Indeed, the explicit question that elicits business expectations on how their turnover or level of employment, for example, may be affected by legislative changes differs in scale from the outputs of our analysis. That detailed analysis brings together evidence from multiple survey queries and additional reports, constituting the main methodology that has been followed for this study.

Table 5-5 below provides a summary of these expectations from companies surveyed and a brief comparison with the outputs of the 'implicit' analysis carried out for this study.

Table 5-5 Sectoral indicators selected for the baseline characterisation

Theme	Findings
Output (Turnover)	Large businesses that participated in the survey expect a significant decline in their output and turnover because of the implementation of the policy options considered –a total reduction of 3% each year, on average, during the first decade from adoption. This direction of impact is in line with findings from the analysis, albeit the scale of impact is larger. This difference in scale could be driven by: (1) assuming full and immediate implementation of policies considered, (2) the complexity in estimating such impacts, and/or (3) not having taken into account the extent to which substitution, reformulation and derogations would take place. Small and medium-sized business (SMEs) survey respondents also expect a decline in their output and turnover from the adoption of the policy options considered, albeit with a lower magnitude. This is also in line with findings from the 'implicit' analysis carried out and could be explained by their expectation that they are likely to substitute products affected with significantly higher likelihood than larger businesses.

Theme	Findings
Intermediate consumption and OPEX	Surveyed companies considered that their intermediate consumption and operating costs are likely to increase during the decade from adoption, which is expected for the operations that are retained after adjusting the business size with the restrictions that cannot be addressed through substitution, reformulation and/or derogations, as reported. Larger businesses expect relatively more increases in operating costs than SMEs.
CAPEX and R&D expenditure	Surveyed businesses also expect CAPEX and R&D to decline when compared to the baseline, but with a lower magnitude, that is, less so than their reductions in operations. This means, again, that the retained business will invest more in capital and R&D per unit of turnover after the adoption of the legislative proposals. The 'implicit' analysis highlights that businesses are likely to reduce their capital investment less than they might expect, based on their responses, and this is because the overall decline is mitigated by increasing requirements especially related to substitution and reformulation.
Regulatory burden	Large and small businesses expect significant increases in regulatory burden resulting from the adoption of changes to the GRA and CLP, which is in line with the outputs of the 'implicit' analysis. Explicit responses from businesses suggest that the estimated scale of increase in regulatory burden would be higher than the outputs of the 'implicit' analysis. One explanation could be that businesses considered the actual and opportunity costs associated with reducing their operations to be a part of this burden, which would explain their expectations of a relatively higher scale of impact.
Employment	Surveyed large businesses surveyed expect a decline in their level of employment, albeit lower than the effects they anticipate on turnover –a total reduction of around 1% each year, on average, during the first decade from adoption–. That is expected given rigidities in the labour market, delays in adjustment and additional employment needs from the legislative changes which net out any reductions due to changes in business size (including to manage more regulatory processes, transition into new or adjusted manufacturing processes, etc.). This decline would be, once more, larger in magnitude that the outputs of the implicit analysis, likely for reasons similar to those already mentioned. SMEs that participated in the survey expect a decline in their levels of employment from the adoption of the policy options considered, albeit with a lower magnitude than larger businesses. This is also in line with findings from the 'implicit' analysis carried out and could be explained by their expectation that their business size may be affected but significantly less so than larger businesses.

5.3 Other business and economic impacts

This section explores other business and economic impacts, including how the policy options may affect the EU chemicals sector's competitiveness (section 5.3.1), its role in international trade (section 5.3.2) and illicit trade (section 5.3.3).

5.3.1 Competitiveness

The competitiveness of the EU chemicals industry has a key role to play in its success as it operates in a global and competitive market. The industry's competitiveness depends on multiple factors, including:

- The capacity to innovate
- Technological development[148]
- The skillset and the cost of the workforce[149]
- Operating/administrative costs[150]
- EU regulations, both for chemicals and other aspects such as emissions regulations[151]
- The effective enforcement of these regulations[152]
- Coordination and communication[153]
- The ease of access to markets[154]

A 2015 study by the Centre for Strategy and Evaluation Services (CSES) et al. considered the impact of REACH on competitiveness and presented the following results from a consultation on the change in competitive positioning due to the introduction of REACH[155]:

- 73% of all manufacturers said their competitive position was weakened by the introduction of REACH
- 59% of Article suppliers considered their position strengthened
- Strongly negative views outweighed the strongly positive views with regards to the effect of REACH on the organisation's competitive position
- Large firms tended to have a more negative view in comparison to smaller firms

Eurometaux also commented that the 2018 REACH registration costs were accommodated by a reduction in profits so as to stay competitive with respect to companies external to the EU. This provided a competitive advantage to companies external to the EU. Although these estimations are REACH focused, other EU chemicals legislation may be expected to follow a similar pattern.

Evidence also suggests that each development of the EU chemical acquis over the last 20 years has produced a more transparent system for communication, and this has benefitted innovation and collaboration within the EU by helping the EU chemical industry to stay competitive globally[156,157]. That said, if regulations are not well designed, the administrative burden can weigh heavily on businesses, especially on SMEs.

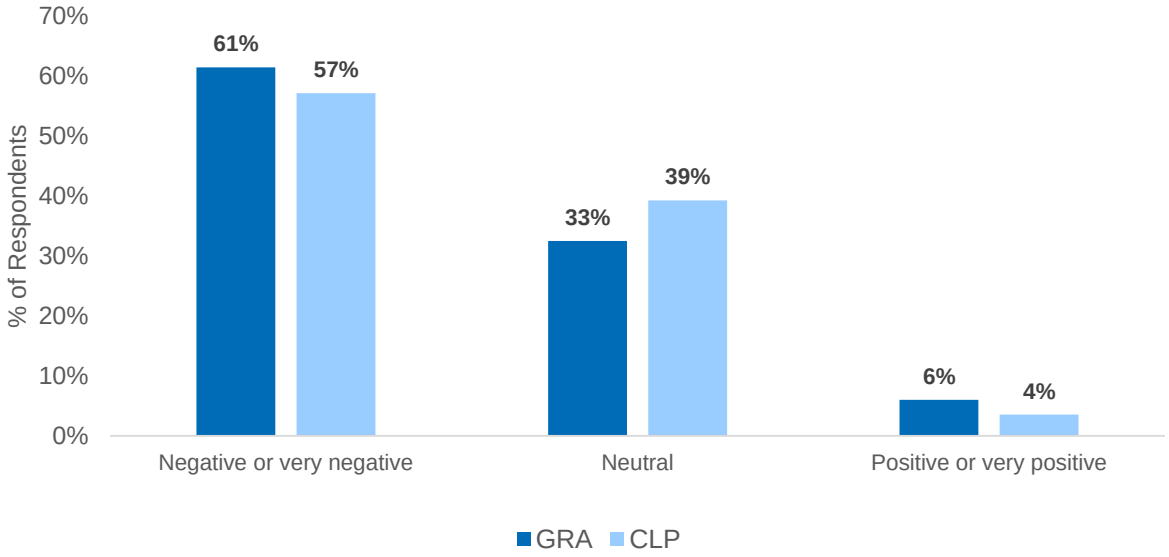
CSES et al. (2015) and Milieu et al. (2017) also agree that operational costs have the most prominent influence on competitiveness. Energy costs are a major influence on profit, with many companies stating the costs are likely to be at least partially absorbed by profit margins. This is confirmed by the outputs of the survey of chemical companies.

[148] Ibid footnote 73
[149] Ibid footnote 73
[150] Ibid footnote 36
[151] Ibid footnote 36
[152] Ibid footnote 73
[153] Ibid footnote 73
[154] Centre for Strategy and Evaluation Services et al, (2015) *Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs.* Available from: monitoring-the-impacts-of-reach.pdf (rpaltd.co.uk)
[155] Ibid
[156] Ibid footnote 73
[157] Ibid footnote 73

In Cefic Facts and figures (2021)[158], competitiveness was assessed with respect to chemical exports. From 2008 to 2018, the proportion of chemical exports from the EU-27+UK decreased by 3.4 percentage points, from 21.6% to 18.2%. In parallel, emerging economies, especially China, have gained market share in the world exports of chemicals. Additionally, when regulation of imported articles is not properly enforced, companies external to the EU have a competitive advantage[159].

Looking ahead to the implementation of the CSS, chemical companies were asked whether the proposed legislative changes to the chemicals sector are expected to affect their competitiveness. Over half of the survey participants responded 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. Survey participants expect similar effects from changes to the GRA and CLP. This is illustrated in the Figure below.

Figure 5-8 Business expectations about the impact of changes of the GRA and CLP on their competitiveness



A.I.S.E.[160] has also recently noted that many organisations have commented on the introduction of the term "essential use" stating that "*essentiality*" may lead to "*impaired competitiveness*".

There could also be some advantages to the introduction of new EU chemicals legislation. For example, the "*first mover competitive advantage*"[161] allows the EU chemical industry to stay ahead of their competitors and reap the benefits once countries external to the EU-27 introduce similar restrictions. It provides companies with the competitive edge to secure intellectual property rights and develop portfolio alternatives ahead of competitors.

5.3.2 International trade

In the context of this study, exports refer to substances, mixtures and articles produced in the EU-27 but sold to a buyer outside the EU-27. In the baseline, exports of the EU chemicals industry are estimated to grow. Nevertheless, the EU chemicals industry is losing share in the world exports of chemicals, currently at around 18% of world exports. Other markets, especially China, will increase their share in the global trade of chemicals.

The majority of survey respondents (77%) 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

[158] Ibid footnote 118
[159] Ibid footnote 73
[160] A.I.S.E. (2020). Comments on document CA/61/2020, CARACAL 37(17-18 – November 2020)
[161] Ibid footnote 73

the trends identified in the baseline. The EU chemicals sector is likely to continue to lose global market share.

By firm size, large enterprises expect relatively more significant losses than SMEs. It is possible that this is due to smaller companies producing for and primarily targeting the local market, while large multinational companies address a worldwide consumer base. However, these insights have limitations (section 2.7).

Imports refer to a substance, mixture or article produced outside the EU-27 but placed on the market in the EU-27. Survey responses show that a majority of respondents (64%) expect the proposed legislative changes to have an impact on imports into the EU-27 arising from the proposed changes to legislation. In particular, respondents expect that changes to the GRA would reduce imports into the EU-27 significantly, while changes to CLP is estimated to have relatively lower impacts (half the magnitude of the effects from GRA).

5.3.3 Illicit trade

Illicit trade is a widespread preoccupation among chemical companies responding to the survey. The majority, or 86%, of participants expect an increase in illicit imports of professional and consumer products into the EU-27 as a result of the decrease in product availability due to the changes to the GRA and CLP. Among the reasons expressed for this expectation are:

- The belief that consumers will easily access imports of non-compliant products online;
- The lack of approved analytical methods or any other realistic way to control or enforce compliance for imports by customs authorities, in addition to it being potentially costly and time-consuming;
- Importing companies' lack of awareness of local rules;
- The same manufacturing activity of SVHCs can take place elsewhere without regulatory burden and be illicitly imported to the EU;
- Illicit exports of chemicals already being a reality in the EU;
- An existing trend among consumers to seek out products that are better performing, despite the presence of hazardous substances.

For an overview of the illicit trade of chemicals into the EU-27 in the past, the EU rapid alert system for dangerous non-food products can be queried. The Cefic Facts and Figures report highlights the most dominant chemical exporters from 2008-2018 globally to be the Unites States, China, South Korea and Japan (excluding Europe). When considering the number of chemical products that have been alerted due to a chemical risk from these exporters, the following was found[162]:

- 171 products came from the Unites States
- 122 products came from the People's Republic of China
- 1 product was exported from South Korea
- 8 products were exported from Japan

A vast number of the alerted products imported from the United States were tattoo inks, whereas the products from China varied from glue to perfume.

Pesticides are heavily regulated within the EU. The European Union Intellectual Property Office estimated in 2017 that the annual revenue losses attributable to counterfeit pesticides equated to 1.3 billion euros[163]. The 2020 report on The Illegal Trade of Chemicals by UNEP labelled Europe as the "*preferred market for the illegal trade in pesticides*".

[162] European Commission,(n.d.) *Safety Gate: the EU rapid alert system for dangerous non-food products*, [Online] Available from: https://ec.europa.eu/safety-gate-alerts/screen/search?resetSearch=true
[163] UNEP and GRID-Arendal (2020). *The Illegal Trade in Chemicals*. Available from: Illegal Trade in Chemicals | UNEP - UN Environment Programme

6 Conclusions

A targeted consultation with the chemicals industry and economic analysis reveals that changes to the GRA and CLP are likely to have significant impacts on the EU chemicals sector and the wider economy. In particular, **EU chemical companies are estimated to lose between €47 billion to €81 billion per year on average between 2023 and 2040, when compared to baseline projections.** In 2040, sectoral turnover in any of the scenarios considered in this study where the proposed changes to CLP and GRA are adopted is estimated to be around €80 billion lower than the baseline.

These estimated losses are significant despite already accounting for the actions that businesses would take to mitigate the effects of the legislative changes, such as substitution, reformulation and/or application for derogations. For example, businesses have suggested that they would be able to substitute and/or reformulate around 30%-35% of the portfolio of products that could be affected by the policy changes.

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 and 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.**

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 to 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. 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.

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 6-1 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 delay on substitution/ reformulation)
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

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 delay on substitution/ reformulation)
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 **74% of products in scope** to be impacted by the addition of hazards to CLP and the extension of the GRA are **professional or consumer products**. 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 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"[164].

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.

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 addition of hazards to CLP and the extension of the GRA 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.

[164] Ibid footnote 28

Appendices

A1 Political and Legal Context

A1.1 CLP Regulation and the UN GHS

In 1992, the UN Conference on Environment and Development (UNCED) in Rio de Janeiro put forward the need to develop a universal system to identify and communicate the presence of hazardous chemicals. [165] Although the EU had already implemented a strong **and robust system of classification and labelling, different jurisdictions around the world had used different systems for the classifications and labelling of diverse preparations and mixtures of chemicals.**[166] **Although many of the hazards communication requirements were similar, some regions saw significant** differences. The following three hazard communication elements were considered as essential to ensure safe use and handling and therefore must appear on Safety Data Sheets (SDS) and labels[167]:

- Physicochemical hazards (explosive, oxidising and flammable properties)
- All toxicological properties of substances and preparations, which may constitute a risk during normal handling or use (effects on human health); and
- Ecotoxicological hazards (acute or long-term toxicity to aquatic or non-aquatic ecosystems).

Companies involved in the international trade of chemicals had to follow stringent laws and regulations in each of the different countries of operation and prepare different labels and Safety Data Sheets (SDS) for each of the separate jurisdictions.[168] As a result of the extensive global trade in chemicals and the need to develop national programmes ensuring the safe use, transport and handling of chemicals by emergency response teams, the UN GHS was implemented by the United Nations (UN) in July 2003, with the World Summit on Sustainable Development encouraging governments to implement the new system as soon as possible (with a view to it being fully operational by 2008).[169]

The GHS now consists of three main elements, which are merged into one system.[170] These are as follows:

- A globally harmonised classification system for chemical substances
- A globally harmonised classification system for mixtures/preparations
- A globally harmonised system for hazard communication for workers, consumers and in transport.

The GHS has allowed for a greater protection of human health and the environment at an international level and has provided a classification framework for countries that did not have a classification and labelling system.[171] The UN GHS is based on a building block approach which provides participating countries with the hazard classes and categories for which they can form their regulatory approach to hazard classification and communication. [172]

[165] UK Health and Safety Executive. (n.d.) *Background: Globally Harmonized System (GHS).* Available from: https://www.hse.gov.uk/chemical-classification/legal/background-directives-ghs.htm
[166] European Commission. (n.d.) *Classification and labelling (CLP/GHS).* Available from: https://ec.europa.eu/growth/sectors/chemicals/classification-labelling_en
[167] European Chemicals Agency (ECHA). (2020). *Guidance on the compilation of safety data sheets*. Available from: https://echa.europa.eu/documents/10162/23047722/guidance_sds_v40_peg_en.pdf/42dc8be5-b033-3062-8ee8-6d3a1b8dcb99
[168] Ibid footnote 36
[169] Ibid footnote 166
[170] United Nations Economic Commission for Europe (UNECE), (2011). *Globally Harmonized System of Classification and Labelling of Chemicals (GHS).* Available from: https://unece.org/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf
[171] United Nations Economic Commission for Europe (UNECE). (n.d.). *About the GHS*. Available from: https://unece.org/about-ghs
[172] Di Prospero Fanghella, P., and Catone, T. (2011). *The CLP Regulation: origin, scope and evolution*. *Ann Ist Super Sanità*, 47(2), pp. 126-131. Available from: https://www.scielosp.org/pdf/aiss/2011.v47n2/126-131/en

The three main hazard groups within the UN GHS are[173]:

- physical hazards.
- health hazards; and
- environmental hazards.

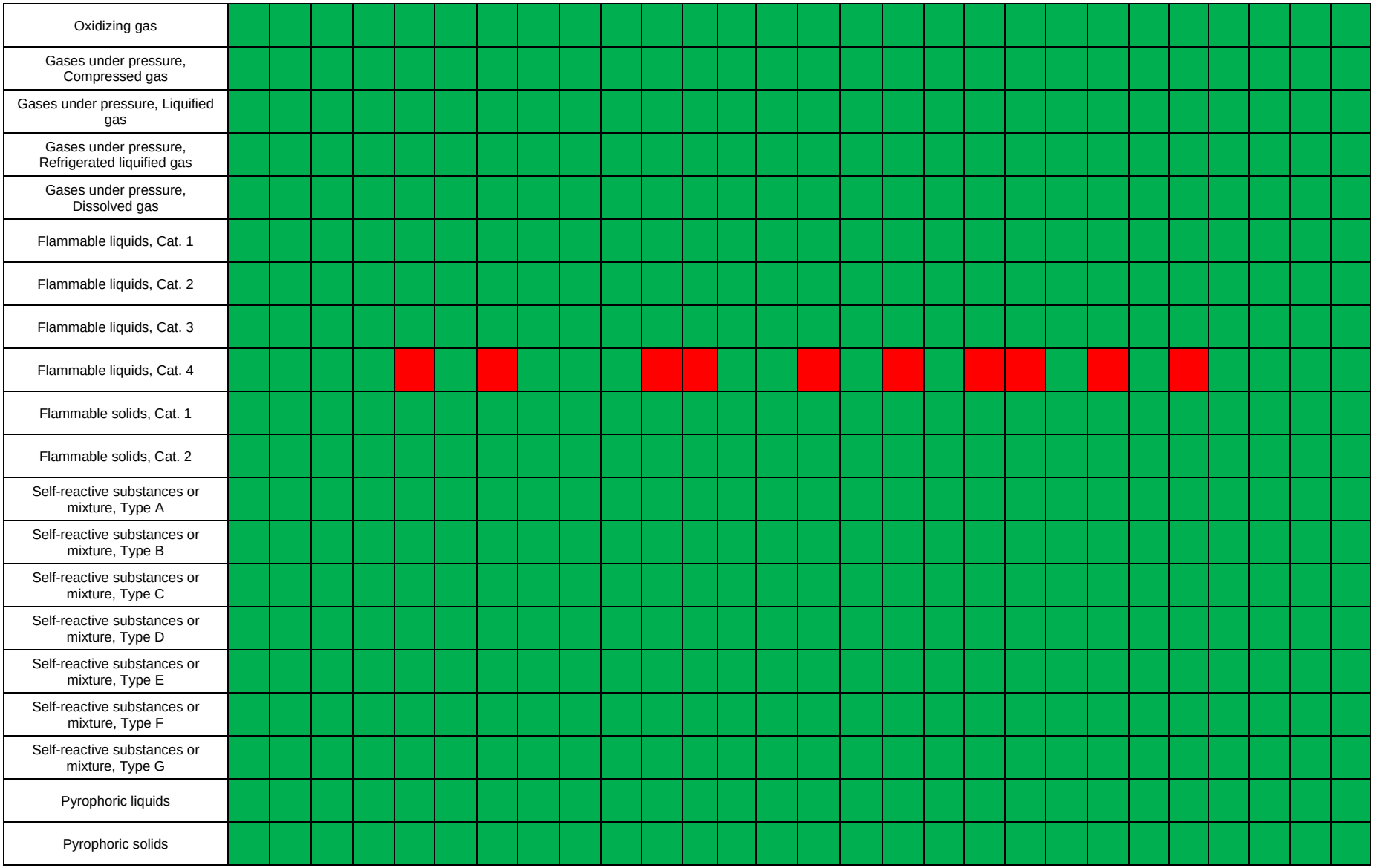
A1.1.1 Global implementation of UN GHS – what "building blocks" have other non-EU countries/ regions adopted, what is our current divergence from other regions?

Table 6-2 below illustrates the differences and the building blocks adopted by each respective country or region.

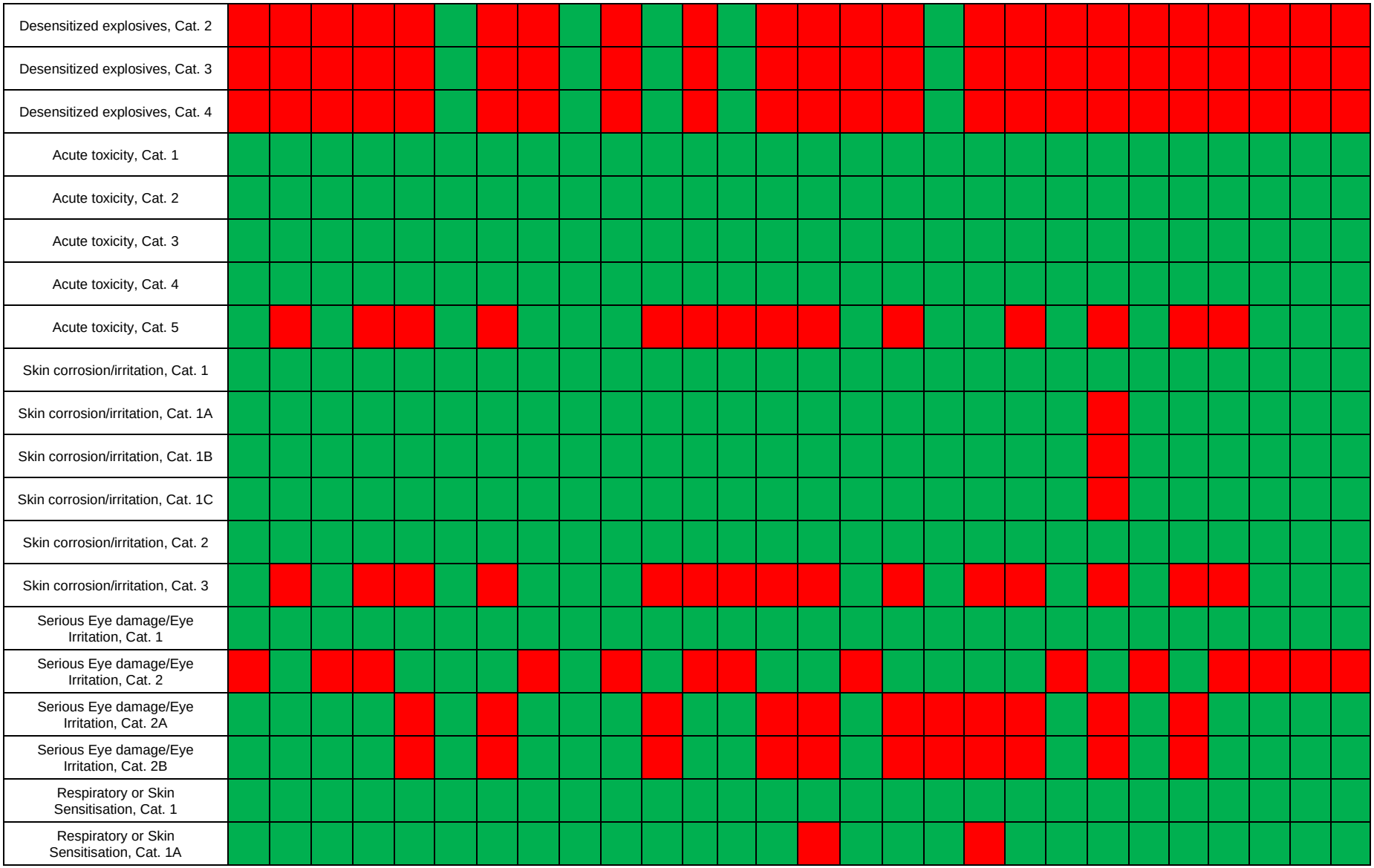
[173] Canadian Centre for Occupational Health and Safety (CCOHS). (n.d.) *Globally Harmonized System (GHS).* Available from: https://www.ccohs.ca/oshanswers/chemicals/ghs.html#:~:text=Hazard%20group%20%E2%80%93%20While%20not%20given,%E2%80%93%20health%2C%20physical%20and%20environmental

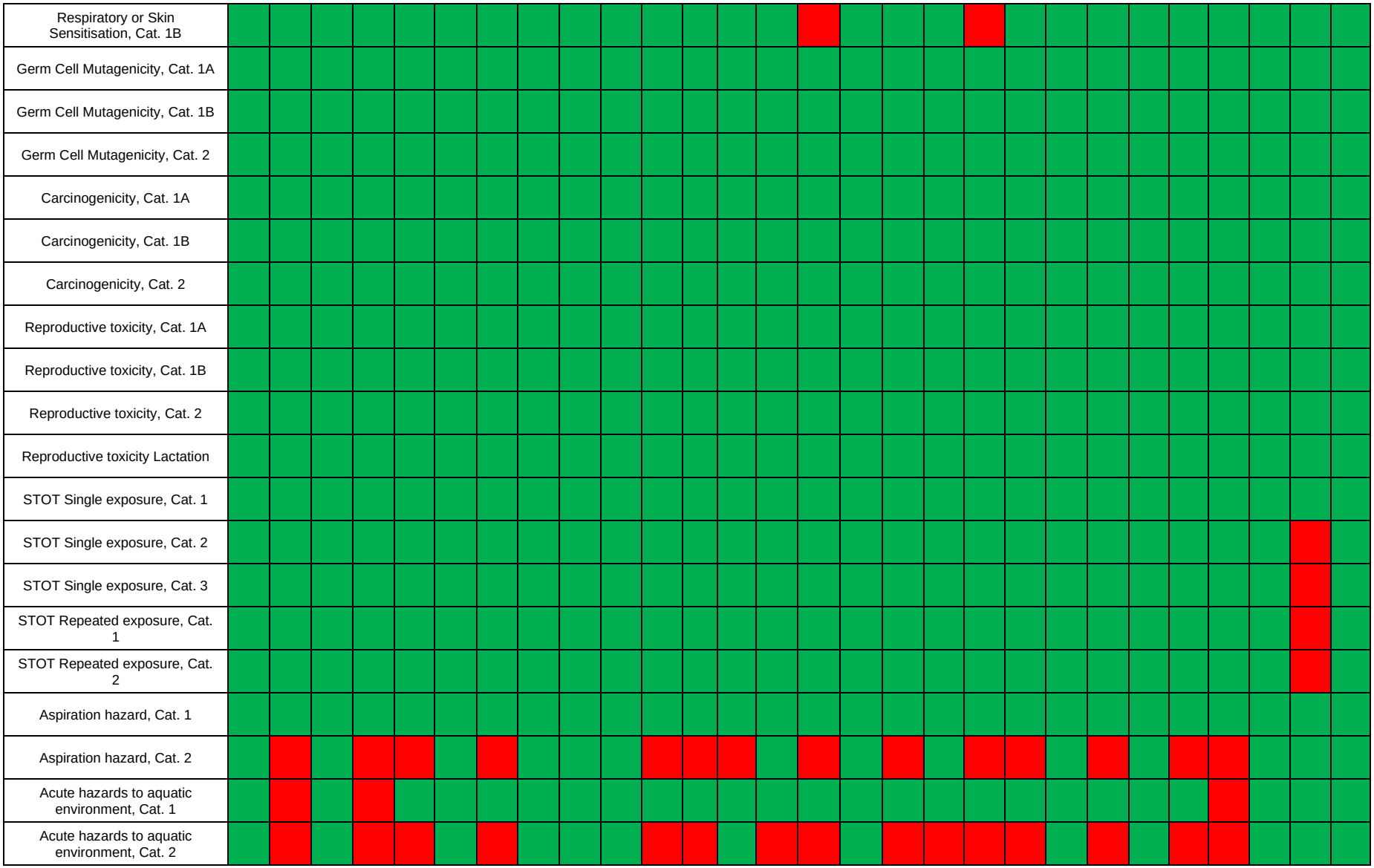
Table 6-2 Adoption of UN GHS (2021)

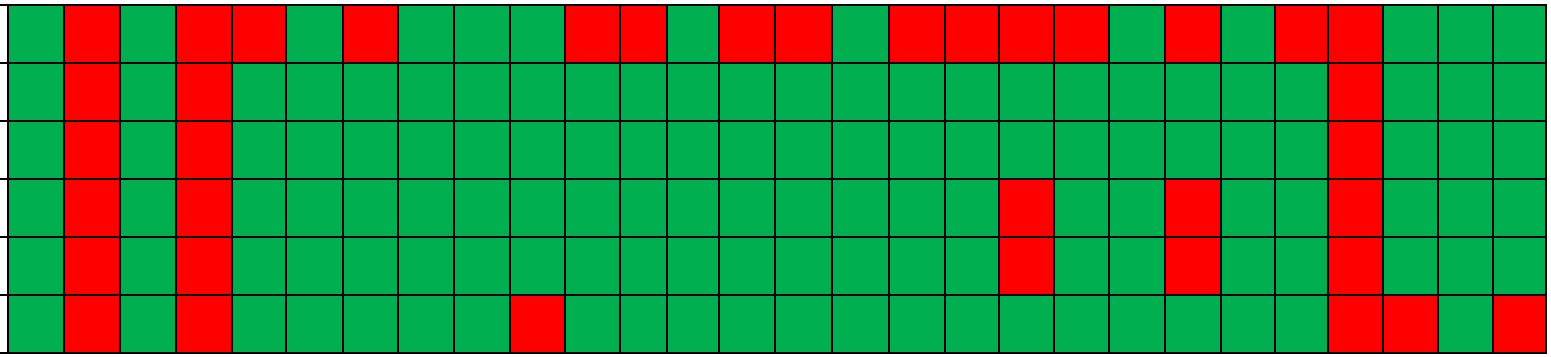
Hazard Classification	AR	AU	BR	CA	CL	CO	CH	CN	CR	EC	EU	ID	JP	KR	MY	MX	NO	NZ	PH	RS	RU	SG	TH	TR	US	UY	VN	ZA
Unstable explosives																												
Explosives, Div1.1																												
Explosives, Div1.2																												
Explosives, Div1.3																												
Explosives, Div1.4																												
Explosives, Div1.5																												
Explosives, Div1.6																												
Flammable gases, Cat. 1A																												
Flammable gases, Cat. 1B																												
Flammable gases, Cat. 2																												
Flammable gases, Cat. 1A (Pyrophoric Gas)																												
Flammable gases, Cat. 1A (Chemical Unstable gases, Cat. A)																												
Flammable gases, Cat. 1A (Chemical Unstable gases, Cat. B)																												
Aerosol, Cat. 1																												
Aerosol, Cat. 2																												
Aerosol, Cat. 3																												
Chemicals under pressure, Cat. 1																												
Chemicals under pressure, Cat. 2																												
Chemicals under pressure, Cat. 3																												


Oxidizing gas
Gases under pressure, Compressed gas
Gases under pressure, Liquified gas
Gases under pressure, Refrigerated liquified gas
Gases under pressure, Dissolved gas
Flammable liquids, Cat. 1
Flammable liquids, Cat. 2
Flammable liquids, Cat. 3
Flammable liquids, Cat. 4
Flammable solids, Cat. 1
Flammable solids, Cat. 2
Self-reactive substances or mixture, Type A
Self-reactive substances or mixture, Type B
Self-reactive substances or mixture, Type C
Self-reactive substances or mixture, Type D
Self-reactive substances or mixture, Type E
Self-reactive substances or mixture, Type F
Self-reactive substances or mixture, Type G
Pyrophoric liquids
Pyrophoric solids

Self-heating substances or mixtures, Cat. 1																											
Self-heating substances or mixtures, Cat. 2																											
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 1																											
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 2																											
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 3																											
Oxidizing liquids, Cat. 1																											
Oxidizing liquids, Cat. 2																											
Oxidizing liquids, Cat. 3																											
Oxidizing solids, Cat. 1																											
Oxidizing solids, Cat. 2																											
Oxidizing solids, Cat. 3																											
Organic peroxides, Type A																											
Organic peroxides, Type B																											
Organic peroxides, Type C																											
Organic peroxides, Type D																											
Organic peroxides, Type E																											
Organic peroxides, Type F																											
Organic peroxides, Type G																											
Corrosive to metals																											
Desensitized explosives, Cat. 1																											


Desensitized explosives, Cat. 2
Desensitized explosives, Cat. 3
Desensitized explosives, Cat. 4
Acute toxicity, Cat. 1
Acute toxicity, Cat. 2
Acute toxicity, Cat. 3
Acute toxicity, Cat. 4
Acute toxicity, Cat. 5
Skin corrosion/irritation, Cat. 1
Skin corrosion/irritation, Cat. 1A
Skin corrosion/irritation, Cat. 1B
Skin corrosion/irritation, Cat. 1C
Skin corrosion/irritation, Cat. 2
Skin corrosion/irritation, Cat. 3
Serious Eye damage/Eye Irritation, Cat. 1
Serious Eye damage/Eye Irritation, Cat. 2
Serious Eye damage/Eye Irritation, Cat. 2A
Serious Eye damage/Eye Irritation, Cat. 2B
Respiratory or Skin Sensitisation, Cat. 1
Respiratory or Skin Sensitisation, Cat. 1A


Respiratory or Skin Sensitisation, Cat. 1B
Germ Cell Mutagenicity, Cat. 1A
Germ Cell Mutagenicity, Cat. 1B
Germ Cell Mutagenicity, Cat. 2
Carcinogenicity, Cat. 1A
Carcinogenicity, Cat. 1B
Carcinogenicity, Cat. 2
Reproductive toxicity, Cat. 1A
Reproductive toxicity, Cat. 1B
Reproductive toxicity, Cat. 2
Reproductive toxicity Lactation
STOT Single exposure, Cat. 1
STOT Single exposure, Cat. 2
STOT Single exposure, Cat. 3
STOT Repeated exposure, Cat. 1
STOT Repeated exposure, Cat. 2
Aspiration hazard, Cat. 1
Aspiration hazard, Cat. 2
Acute hazards to aquatic environment, Cat. 1
Acute hazards to aquatic environment, Cat. 2

Acute hazards to aquatic environment, Cat. 3	
Long-term hazards to the aquatic environment, Cat. 1	
Long-term hazards to the aquatic environment, Cat. 2	
Long-term hazards to the aquatic environment, Cat. 3	
Long-term hazards to the aquatic environment, Cat. 4	
Hazard to the ozone layer	

Source: DHI (2021) GHS implementation(*) - Compare hazard building blocks. Available at: http://ghs.dhigroup.com/GHSImplementatationCompare.aspx

Key	
Building block implemented or can be used (voluntarily)	
Building block not implemented	
GHS not implemented or no information available	

A1.2 Generic Approach to Risk Management

The 2017 Fitness Check on CLP investigated the possible risk management measures following classification according to the CLP regulation. Four possibilities were defined in the report; these possibilities align with the GRA, the GRA with derogations, SRA approach, and further implementation approaches. The further implementation approach refers to when an implementation step is required, which may entail further assessment by an economic operator or regulatory action by the Member States.[174]

Table 6-4 provides and overview of the implementation of the generic approach to risk management and the specific risk approach.

Table 6-3 Overview of Risk Management Approaches in EU Chemicals Policy[175]

Legislative Act	GRA	GRA with derogation	SRA	Further implementation
REACH Regulation	x	x	x	
Consumer				
Regulation (EC) No 1223/2009 on cosmetic products	x	x	x	
Directive 2009/48/EC on the safety of toys	x	x	x	
Directive 2014/40/EU on manufacture, presentation and sale of tobacco	x			
Regulation (EC) No 450/2009 on active and intelligent materials	x		x	
Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food	x		x	
Regulation (EC) No 648/2004 on detergents	x		x	
Professional				
Regulation (EC) No 1107/2009 on plant protection products	x	x	x	x
Regulation (EU) No 528/2012 biocidal products	x	x	x	x
Directive 2014/68/EU pressure equipment	x		x	
Environmental protection				

[174] Ibid footnote 36
[175] Output derived from Ibid footnote 33

Legislative Act	GRA	GRA with derogation	SRA	Further implementation
Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals	x			
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso III)	x			x
Directive 2010/75/EU on industrial emissions	x		x	x
Directive 2008/98/EC on waste				x
Directive 1999/31/EC on the landfill of waste				x
Directive 2000/53/EC on end-of life vehicles	x			
Regulation (EC) No 1013/2006 shipments of waste	x			
Directive 2004/35/CE on environmental liability	x			
Directive 2011/65/on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)	x		x	
Directive 2006/66/ on batteries and accumulators	x			
European Parliament and Council Directive 94/62/EC on packaging and packaging waste	x			
Directive 2012/19/on waste electrical and electronic equipment (WEEE)			x	
Regulation (EU) 2019/1021 Persistent organic pollutants Regulation	x			
Directive 2008/50/EC on ambient air quality and cleaner air for Europe			x	
Directive 2000/60/EC establishing a framework for Community action in the field of water policy	x		x	

Legislative Act	GRA	GRA with derogation	SRA	Further implementation
Directive (EU) on the quality of water intended for human consumption (recast)	x		x	
Council Directive 91/271/EEC concerning urban waste-water treatment			x	
OSH				
Directive 92/85/EEC pregnant workers				x
Directive 94/33/EC young people at work	x			
Directive 98/24/EC chemical agents at work			x	x
Directive 2004/37/EC carcinogens or mutagens at work			x	x
Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos at work			x	
Product Control				
Directive 93/42/EEC concerning medical devices			x	
Directive 98/79/EC on in vitro diagnostic medical devices			x	
Council Directive 75/324/EEC relating to aerosol dispensers			x	
Directive 2014/28/EU of the European Parliament relating to the making available on the market and supervision of explosives for civil uses (recast)	x		x	
Regulation (EC) No 2003/2003 relating to fertilisers			x	
Regulation (EC) No 66/2010 on the EU Ecolabel	x		x	

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

Table 6-4 Current application of GRA per Sector and Assumed Future Application of GRA

Classification	Carc	Carc.	Muta	Muta.	Repro	Repro.	PBT/vPvB	ED	PMT	Resp sens.	Resp sens.3	Resp sens.2	STOT SE	STOT SE6	STOT RE	STOT RE7	Immuno	Neuro	Skin sens.	Skin sens.3	Skin sens.2	Aquatic chronic	Aquatic chronic9
Category	**1 A/B**	**2**	**1 A/B**	**2**	**1 A/B**	**2**				**1**	**1A**	**1B**	**1**	**2**	**1**	**2**			**1**	**1A**	**1B**	**1**	**2**
Current classifications	**932**	**200**	**428**	**144**	**206**	**148**	88	89	N/A	116	0	0	14	7	182	352	N/A	N/A	1050	21	14	1036	576
PC1 Adhesives, sealants	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC3 Air care products	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC4 Anti-Freeze and de-icing products	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC8 Biocidal products	Co *	Co**	Co *	Co**	Co *	Co**	Co *	Co *	Co**	Co**	Co**	Co**	Co*	Co**	Co*	Co**	Co*	Co*	Co**	Co**	Co**	Co**	Co**
	P*		P*		P*		P*	P*	P **														
PC9a Coatings and paints, thinners, paint removers	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC9b Fillers, putties, plasters, modelling clay	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC9c Finger paints	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC12 Fertilizers	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC18 Ink and toners	Co *	Co**	Co *	Co**	Co*	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC23 Leather treatment products																							
	P **		P **		P **		P **	P **	P **														

Classification	Carc	Carc.	Muta	Muta.	Repro	Repro.	PBT/vPvB	ED	PMT	Resp sens.	Resp sens.3	Resp sens.2	STOT SE	STOT SE6	STOT RE	STOT RE7	Immuno	Neuro	Skin sens.	Skin sens.3	Skin sens.2	Aquatic chronic	Aquatic chronic9
PC24 Lubricants, greases, release products	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC25 Metal working fluids																							
	P **		P **		P **		P **	P **	P **														
PC26 Paper and board treatment products																							
	P **		P **		P **		P **	P **	P **														
PC27 Plant protection products	Co *	Co **	Co *	Co **	Co *	Co **	Co *	Co *	Co**	Co **	Co**	Co **	Co **	Co **	Co **	Co **	Co **	Co **	Co **	Co **	Co **	Co* *	Co**	Co **
	P*		P*		P*		P*	P*	P **														
PC28 Perfumes, fragrances	Co *	Co *	Co *	Co *	Co *	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC31 Polishes and wax blends	Co *		Co *		Co *																		
	P **		P **		P **		P **	P **	P **														
PC32 Polymer preparations and compounds	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC34 Textile dyes, and impregnating products	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC35 Washing and cleaning products	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC36 Water softeners	Co *	Co**	Co *	Co**	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														
PC37 Water treatment chemicals																							
	P **		P **		P **		P **	P **	P **														

Classification	Carc	Carc.	Muta	Muta.	Repro	Repro.	PBT/vPvB	ED	PMT	Resp sens.	Resp sens.3	Resp sens.2	STOT SE	STOT SE6	STOT RE	STOT RE7	Immuno	Neuro	Skin sens.	Skin sens.3	Skin sens.2	Aquatic chronic	Aquatic chronic9
PC38 Welding and soldering products, flux products																							
	P **		P **		P **		P **	P **	P **														
PC39 Cosmetics, personal care products	Co *	Co *	Co *	Co *	Co *	Co *	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**	Co**
	P **		P **		P **		P **	P **	P **														

Key	
	REACH Restriction (Article 68(2)) - current
	REACH Restriction (Article 68(2)) - future
	Sector specific legislation - current
	Sector specific legislation - future
Co	Consumer products
P	Professional use products
*****	Current legal requirements
******	Future legal requirement

A2 Substance to be Regulated List Methodology

A2.1 Methodology

The methodology for the development of the 'list of substances to be regulated' can be broken down into five steps:

1. Collection of information sources and conversion into lists
2. Development of rulesets to determine substances to be regulated assignments for collected lists
3. Development of Excel tool to perform substances to be regulated determinations by screening substances against collected lists and rulesets
4. Loading of a list of substances at the "front end" for evaluation
5. Clean-up of the list of substances to be regulated

Due to numerous factors, the list as developed has the potential to either over- or under-estimate the actual number of substances to be regulated on the EU market. Potential reasons for over-estimation include use of screening data and suspected, but not yet confirmed, lists to identify substances as SoC (note that assignments of F1 and F2 have been used to account for relative uncertainty). Reasons for underestimation include incomplete lists of substances loaded at the 'front end' (e.g. polymers and low tonnage substances excluded), data availability and potential future testing of substances, and the impact of the use of grouping approaches for future substance evaluation.

A2.2 Information sources and development of rule sets

Information pertaining to the hazardous properties of substances was collected from various sources. Each information source was assessed for its relevance to provide information on one or more relevant hazard classifications. The information sources included:

- European regulatory databases (e.g. ECHA, EFSA)
- Other regulatory databases (e.g. US EPA, Australia)
- Other internationally recognised information sources, e.g. National Institute for Occupational Safety and Health (NIOSH), ChemSec Substitute-It-Now (SIN) List
- Published lists of substances e.g. REACH sector group listings
- Published literature (peer reviewed and grey literature)

A description of each information source used in the exercise is provided in Appendix 1.

A set of rules was developed determining how each information source would contribute to the determination of SoC classifications of substances. Each information source could potentially lead to a substance being concluded as classified for a given hazard, and each such conclusion was given one of three assignments – "C", "F1" or "F2" – depending on the specific information source:

- **"C" Current substances to be regulated**: substances recognized in EU as fulfilling the criteria for a hazard classification. This can be due to formal identification on a regulatory list pursuant to an administrative decision (e.g. SVHC candidate list, CLH list), a regulatory opinion or decision taken by an EU or Member State authority in the context of a specific

evaluation (e.g. endocrine disruptors), or a self-classification by the economic operator(s) responsible for placing the substance on the market (e.g. REACH registered classification).

- **Future substances to be regulated**: substances that are not recognized as a substances to be regulated in the EU (not in "C" category) but which might be recognized as such in the future, depending on a number of uncertainties including the implementation of the European Commission's EU Chemical Strategy for Sustainability (CSS). This encompasses:
    - **"F1"** 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"** 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).

A summary of each information source and its contribution to the determination of the hazard classifications for substances to be regulated is given in the tables below.

Table 6-5. Summary of lists used by Ricardo. These include EU regulatory lists on industrial chemicals, biocides and plant protection products, SIN List, and sources providing information on PBT, vPvB, PMT and vPvM classifications. Asterisk (*) indicates that source contains multiple assignments (C, F1 or F2) and colour indicates highest priority (C > F1 > F2).

List	Source	Endpoint	No. of subs
Harmonised classification and labelling	ECHA	Various	3,843
REACH registered classification and labelling	ECHA	Various	9,004
Candidate list of SVHC for authorisation	ECHA	Various	393
Substance evaluation (CoRAP) *	ECHA	Various	376
ED assessment *	ECHA	ED	129
PBT assessment *	ECHA	PBT/vPvB	223
Substances subject to POPs regulation	ECHA	PBT/vPvB	86
Previous biocidal AS potential candidates for substitution *	ECHA	Various	42
RMOA	ECHA	Various	279
Registry of CLH intentions until outcome	ECHA	Various	156
Substances proposed as POPs	ECHA	PBT/vPvB	47
Pesticide AS candidate for substitution *	European Commission	Various	26
SIN list (all chemicals)	ChemSec	Various	991
'Red' (potentially PBT) substances	UBA (2020) PBT - Quo vadis? Examination and further development of the PBT assessment approach for identification of environmental SVHC	PBT	8
PaqMT, PaqM with suspected T, and suspected PaqMT substances *	UBA (2018) Assessment of persistence, mobility and toxicity (PMT) of 167 REACH registered substances	PMT	134
PMT/vPvM assessments for all REACH registered substances (May 2017) reported in drinking water or groundwater *	UBA (2019) Protecting the sources of our drinking water. The criteria for identifying Persistent, Mobile, and Toxic (PMT) substances and very Persistent, and very Mobile (vPvM) substances under EU REACH Regulation (EC) No 1907/2006	PMT/vPvM	87
P assessments of 7 substances found in surface water	KWR (2020) Persistence of gabapentin, 1H-benzotriazole, diglyme, DTPA, 1,4-dioxane, melamine and urotropin in surface water	vPvM	7
M/vM substances (min log Kow/Dow <4.5, log Koc <4)	Arp et al. (2017) Ranking REACH registered neutral, ionizable and ionic organic chemicals based on their aquatic persistency and mobility	PMT/vPvM	9,032
P/vP substances (biodegadation score of 3 or 4)	Arp et al. (2017) Ranking REACH registered neutral, ionizable and ionic organic chemicals based on their aquatic persistency and mobility	PMT/vPvM	4,762
PBT screening of REACH registered chemicals (up to 2012	Strempel et al. (2012) Screening for PBT Chemicals among the “Existing” and “New” Chemicals of the EU	PBT	33
'Iceberg' substances	UBA (2020) PBT - Quo vadis? Examination and further development of the PBT assessment approach for identification of environmental SVHC	PBT/vPvB	11
PetCo potential PBT substances	Concawe, LOA and HCSC	PBT/vPvB	118
PFAS vPvM vPvB list	Global database of PFAS (2018)	vPvB/vPvM	4,729
P/vP screening (not readily biodegradable)	eChemPortal	PBT/vPvB/PMT/vPvM	3,590
P/vP (soil, sed, water simulation tests)	eChemPortal	PBT/vPvB/PMT/vPvM	65
B/vB screening (log Kow)	eChemPortal	PBT/vPvB	832
B (experimental BCF/BAF)	eChemPortal	PBT/vPvB	57
vB ((experimental BCF/BAF)	eChemPortal	PBT/vPvB	45
T (aquatic tox)	eChemPortal	PBT/PMT	1,072
M/vM screening (log Kow)	eChemPortal	PMT/vPvM	3,825
M (experimental Koc)	eChemPortal	PMT/vPvM	1,080
vM (experimental Koc)	eChemPortal	PMT/vPvM	832
Jon Arnot BCF/BAF database (Arnot & Gobas, 2006)	ARC Research and Consultancy	PBT/vPvB	177
Jon Arnot BMF database (Arnot & Quinn, 2015)	ARC Research and Consultancy	PBT/vPvB	101

C
F1
F2

Table 6-6. Summary of lists used by ToxMinds for information on human health and Endocrine Disrupting hazards. Asterisk (*) indicates that source contains multiple assignments (C, F1 or F2) and colour indicates highest priority (C > F1 > F2).

List	Source	Endpoint	No. of subs
AOEC Respiratory sensitizer list	AOEC database	Sens.	291
ATSDR - Health Effects	ToxPlanet	Various	387
Australia - Work Health and Safety Regulations	ToxPlanet	Carc.	20
Boyes - Neurotoxicants	ToxPlanet	Neuro.	148
CalEPA - Cancer Potency Factors (2020 Update)	ToxPlanet	Carc.	174
ChemsafetyPro		ED	45
Colborn List	ToxPlanet	ED	87
Danish EPA		ED	193
Endocrine Disruptor Lists - Substances identified as endocrine disruptors at EU level *	ToxPlanet	ED	111
EPA - Chemicals Evaluated for Carcinogenic Potential	ToxPlanet	Carc.	405
EPA - Endocrine Disruptor Screening Program (EDSP)	ToxPlanet	ED	67
EPA - IRIS - Weight of Evidence (WOE) of Carcinogenicity	ToxPlanet	Carc.	297
EU - Endocrine Disruptors - Annexes	ToxPlanet	ED	609
EU - Regulation No 1907/2006 - Annex XVII	ToxPlanet	Carc., Repro.	1482
European Commission		ED	28
International Panel on Chemical Pollution (IPCP)		ED	77
Known neurotoxicants in man	Grandjean & Landrigran (2006) Developmental neurotoxicity of industrial chemicals	Neuro.	204
MAK Respiratory sensitizer list	MAK report	Sens.	269
NIOSH - Carcinogen List	ToxPlanet	Carc.	133
NTP - 14th Report on Carcinogens (RoC) *	ToxPlanet	Carc.	369
OSHA - 13 Carcinogens	ToxPlanet	Carc.	13
RISCTOX	ToxPlanet	Various	5929
TEDX		ED	1482
Immunotoxicity evaluation of 20 substances	Veraldi et al. (2006) Immunotoxic effects of chemicals: A matrix for occupational and environmental epidemiological studies	Immuno.	20
Workshop Immuno substances	U.S. Congress, Office of Technology Assessment, Identifying & Controlling immunotoxic Substances-Background Paper, OTA-BP-BA-75 (Washington, DC: U.S. Government Printing Office, April 1991).	Immuno.	47

C
F1
F2

The following sections describe how each information source has been processed and considered in the determination of substance classifications.

A2.2.1 ECHA and European Commission lists

A number of ECHA lists were exported from the ECHA website in February and March 2021 and used for identification of current (“C”) and future (“F1”) substances to be regulated. Those substances included on the ‘Candidate list of SVHC for authorisation’, ‘Harmonised classification and labelling’, ‘REACH registered classification and labelling’, and ‘Substances subject to POPs regulation’ lists assigned “C” for their relevant hazard classifications. Substances on the ‘Substance evaluation/Community Rolling Action Plan (CoRAP)’, ‘Endocrine disruptor (ED) assessment’ and ‘Persistent, bioaccumulative and toxic (PBT) assessment’ lists were also assigned “C” for those whose assessment had been concluded and the concern (e.g. EDC HH, PBT, vPvB etc.) confirmed. For those substances on these 3 evaluation/assessment lists which were not yet concluded, a classification of “F1” was used, while substances with an assessment concluded as not fulfilling the suspected hazard were removed.

An additional 3 ECHA lists were used to identify future (“F1”) substances to be regulated: the ‘Registry of harmonised classification and labelling (CLH) intentions until outcome’, ‘Regulatory Management Option Analysis (RMOA)’ and ‘Substances proposed as Persistent Organic Pollutants

(POPs)' lists. Substances with the 'withdrawn' or 'opinion adopted' status in the CLH intentions list were excluded, with the remaining substances being assigned based on their intended classifications proposed by the dossier submitter. Those substances for which there was no need to initiate further regulatory risk management at this time were excluded from the RMOA list, and the rest were filtered based on relevant hazard concerns; exposure, widespread use, and aggregated tonnage concerns were not included. As some of the RMOA concerns were not directly comparable to those hazard classifications in the file, Table 3 below details how these concerns were mapped. For the proposed POPs list, 3 substances already listed under the Stockholm Convention/POPs regulation were removed, as these substances are captured in the 'substances subject to POPs regulation' list above. The remaining 47 substances were mapped as future ("F1") PBT and vPvB.

Table 6-7. Mappings of the relevant concerns from ECHA's Regulatory Management Option Analysis (RMOA) list.

RMOA concern	Future ("F1") classifications
Skin sensitiser	Skin Sens. 1
Respiratory sensitiser	Resp. Sens. 1
STOT RE	STOT RE 1
Carcinogenic	Carc. 1A/1B
Mutagenic	Muta. 1A/1B
Toxic for reproduction	Repro. 1A/1B
Endocrine disruption	EDC HH and EDC ENV
Persistence and bioaccumulation	vPvB
Persistence, bioaccumulation, and any other category	PBT
Persistence and any category other than bioaccumulation	PMT and vPvM
Other environmental toxicity and/or other human toxicity only	ELoC

Persistent, mobile and toxic (PMT), very persistent, very mobile (vPvM), and ED substances on the European Commission's 'Pesticide active substance candidates for substitution' list and ECHA's 'Previous biocidal active substance potential candidates for substitution' list were assigned "F1" for the relevant classifications. Additionally, those pesticide and biocide active substances that met current classifications, such as Carc. 1A or 1B, Repro. 1A or 1B, Repro. 2, vPvB etc., were assigned "C".

ChemSec SIN List

A further source of "F1" substances was the "Substitute-It-Now" (SIN) list provided by the International Chemical Secretariat (ChemSec). This database of substances that are claimed to fulfil ECHA's SVHC criteria were categorised according to the reason for inclusion on the list, e.g. ED, reprotoxic etc., and mapped into the file as "F1" for these hazards.

eChemPortal lists

The eChemPortal was used to identify future ("F1" and "F2") PBT, vPvB, PMT and vPvM substances, based on available study data in the ECHA REACH database. The details of search queries carried out are presented in Appendix 2. The assessments were carried out at two levels: the screening level,

leading to a conclusion of “F2”; and the definitive level, leading to a conclusion “F1”. In order for a substance to be concluded SoC with an assignment “F1”, all data supporting this conclusion (i.e. for P, B, M and/or T) were required to be definitive data. Any conclusions based on one or more pieces of screening information was assigned “F2” by default. In all cases, only studies that were considered to be reliable (Klimisch score 1 or 2) were used. The data sources and rules used for this exercise are detailed below.

Persistence

For determination of P/vP, the definitive data used were experimental simulation biodegradation tests in water, sediment or soil. Half-life cut-offs were selected to take account of recent changes in ECHA guidance concerning the practice of temperature correction of measured degradation half-lives from 20°C to 12°C (general practice since 2013, equates to increasing by a factor 2.2), and the requirement to include non-extractable residues (NER) in the calculation of biodegradation half-lives (required since 2017 update of ECHA R.11 guidance, technical feasibility/implementation discussions ongoing, true impact not yet known).

For the water compartment, as no pre-2013 studies produced half-lives in the range of ½ P – P (20-40 days) it was considered unlikely that temperature correction would impact P/vP conclusions, and as NER are not expected to occur significantly in these tests, a half-life cut-off matching that of the P criterion for water (≥ 40 days) was applied (Table 4). For the soil and sediment compartments a greater proportion of pre-2013 studies had half-lives in the range of ½ P – P (60-120 days). Also, the updated NER guidance is expected to mainly impact the soil and sediment compartments. Therefore, a half-life cut-off equivalent to ½ the soil and sediment P criteria (≥ 60 days) was used for soil and sediment data. Due to the evident uncertainty in the actual half-life data that would be relevant to regulatory decisions, no effort was made to distinguish between P and vP conclusions, and instead the above criteria were used to produce lists of substances considered as meeting both the P and vP criteria.

Table 6-8. Numbers of biodegradation simulation studies found in eChemPortal when applying different half-life cut-offs, corresponding with ½ P (water: 20 days; soil/sediment: 60 days), P (water: 40 days; soil/sediment: 120 days) and vP (water: 60 days; soil/sediment: 180 days). Values in bold indicate the cut-offs used to produce the definitive list of P/vP substances.

	Total hits	> ½ P	> P	> vP
Water	65	19	**16**	15
Sediment	132	**53**	38	35
Soil	170	**55**	41	30

Screening data for P/vP was based on experimental ready biodegradability studies (OECD 301A-F or 310). Any substance with ready biodegradability study data, where the result was not greater than 60%, or that was not concluded “readily biodegradable” based on this study was considered to be screening as P/vP.

Bioaccumulation

For determination of B/vB, the definitive data used were experimental bioaccumulation studies. Various bioaccumulation metrics were considered in these assessments: laboratory bioconcentration factors (BCF), field bioaccumulation factors (BAF) and laboratory biomagnification factors (BMF). Substances were concluded to be B if they had a BCF/BAF result greater than or equal to 2,000, or a

BMF of greater than or equal to 1. Substances were concluded vB if they had a BCF/BAF result greater than or equal to 5,000, or a BMF of greater than or equal to 1.

Screening data to identify potential B/vB substances was based on log K_{ow} values between 4.5 and 10. The lower bound corresponds with the cut-off applied in ECHA guidance, whereas the upper bound is recognised in guidance as a value above which physico-chemical factors may hinder uptake.

Additional definitive B/vB data (applying the same cut-off values as above) was sourced from the BCF/BAF database of Arnot & Gobas (2006) and the BMF database of Arnot & Quinn (2015). In the case of Arnot & Gobas (2006), the database was filtered to remove the low reliability data (overall score 3), as well as data for autotrophs and modelled ecosystems. In the case of Arnot and Quinn (2015), original measured BMFs from studies with overall reliability score of "M" or "H" were used.

Toxicity

For the eChemPortal queries of T, no screening assessment was performed. Definitive data was based on experimental chronic aquatic toxicity studies. An EC_{10}, EL_{10}, NOEC, or NOELR of less than or equal to 0.01 mg/L in long-term toxicity to fish, long-term toxicity to aquatic invertebrates, or toxicity to aquatic algae and cyanobacteria studies was concluded as fulfilling the T criteria. A substance was also deemed as fulfilling the T criteria if it had a "C" or "F1" assignment in one of the following classifications:

- CMR 1A/1B, Repro. 2, STOT RE 1 or 2
- Carc. 2, Muta. 2, Repro. 3 **(PMT only)**
- EDC HH or EDC ENV **(PMT only)**

It should be noted that the T criteria proposed by UBA for the determination of PMT substances differ from those of REACH Annex XIII for determination of PBT substances. Hence separate assessments were needed.

The UBA proposal states:

"evidence for significant risk to human health and the environment for persistent and mobile substances may arise in any of the following situations and need assessment to demonstrate fulfilling the equivalent level of concern of Article 57(f). these indicators are:

e) The substance meets the criteria for classification as carcinogenic (category 2), or germ cell mutagenic (category 2) according to Regulation (EC) No. 1272/2008;
f) The substance meets the criteria for classification as additional category for "effects on or via lactation", according to Regulation (EC) No. 1272/2008;
g) The Derived-No-Adverse-Effect-Level (DNEL) is ≤µg/kg/d (oral, long term, general population), as derived following Annex I;
h) The substance acts as an endocrine disruptor in humans and/or wildlife species according to the WHO/IPCS definition of an endocrine disruptor."[176]

Mobility

Definitive M/vM data was based on experimental log K_{oc} results: M if log K_{oc} of less than or equal to 4, and vM if log K_{oc} of less than or equal to 3. Screening data was based on log K_{ow} values of less than 4.5 at pH 4 to 10. The pH range was applied as proposed in the UBA criteria to account for the influence of ionisation on mobility for ionisable substances. N.B. it was not possible to apply a pH term in the query of log K_{oc} data.

[176] Umweltbundesamt (2019) Protecting the sources of our drinking water: the criteria for identifying persistent, mobile and toxic (PMT) substances and very persistent and very mobile (vPvM) substances under EU Regulation REACH (EC) No 1907/2006

Literature sources of PBT/vPvB and PMT/vPvM substances

UBA lists

Various lists of PBT/PMT substances included in reports by the German Environment Agency (Umweltbundesamt-UBA) were used to identify future "F1" or "F2" PBT, vPvB, PMT and vPvM substances.

One report used was UBA (2018) 'Assessment of persistence, mobility and toxicity (PMT) of 167 REACH registered substances'. The 167 substances were selected from the PROMOTE research project (n = 156) and from a previous UBA research project (Kalberlah et al., 2014) (n = 11). All information, including validated QSARs, was evaluated in a weight-of-evidence approach using expert judgement. This evaluation produced 3 lists we could use: 8 substances assessed as P_{aq}MT, 21 as P_{aq}M with suspected T, and 105 as suspected P_{aq}MT. PMT substances were mapped as "F1" PMT, while the PM with suspected T and suspected PMT substances were mapped as "F2" PMT.

The UBA (2019) report 'Protecting the sources of our drinking water. The criteria for identifying Persistent, Mobile, and Toxic (PMT) substances and very Persistent, and very Mobile (vPvM) substances under EU REACH Regulation (EC) No 1907/2006' was also used. UBA performed a PMT/vPvM assessment for 142 REACH registered substances (as of May 2017) that have been reported in at least one study as detected in groundwater or drinking water. 70 substances were assessed to be potential PMT/vPvM (mapped as "F2" PMT or vPvM), 14 as PMT, 1 as vPvM and 1 as PMT/vPvM (mapped as "F1" PMT, vPvM or PMT/vPvM accordingly).

The final UBA lists came from UBA (2020) 'PBT - Quo vadis? Examination and further development of the PBT assessment approach for identification of environmental SVHC'. Substances detected in environmental monitoring studies in remote areas were assessed for their P and B properties using EpiSuite estimations: 11 substances within this "Iceberg" list were assessed to be potentially PB, PvB, B and vB. This source was treated as a single list used to identify future ("F1") PBT and vPvB substances. UBA (2020) also re-analysed 53 previously suspected PBT/vPvB substances which have been concluded to be non PBT/vPvB by the PBT Expert Group. Of these 53 substances, 8 were "red" (strong indication that a PBT classification could be concluded). These 8 "red" substances were included as a list to identify "F1" PBT substances.

Arp et al. (2017)

A screen for PMT/vPvM substances (both of parent compounds and their predicted transformation products) was conducted based on the supplementary raw data from Arp et al. (2017) 'Ranking REACH registered neutral, ionizable and ionic organic chemicals based on their aquatic persistency and mobility'. The screening of REACH registered chemicals for PMT properties conducted by Arp et al. used earlier PMT criteria that differs to that proposed by UBA, however the raw data was available in the supplementary information, enabling an evaluation using the UBA criteria to be performed. Substances were flagged as P/vP if they had a biodegradation score of 3 or 4, corresponding with a water half-life > 40 days (based on experimental or QSAR data), and as M/vM if either the minimum log K_{ow}/D_{ow} was less than 4.5 or the minimum log K_{oc} value was less than 4. Any substances flagged as both P/vP and M/vM were identified as future ("F2") PMT and vPvM substances. F2 was selected for this information source given the uncertainty associated with extensive use of computational/QSAR predictions (to estimate persistence, ionisation potential, transformation products etc).

Other literature

Estimated P, B and T property screening data from the paper 'Screening for PBT Chemicals among the "Existing" and "New" Chemicals of the EU' by Strempel et al. (2012) was included in part 2 of the Supplementary Material from Arp et al. (2017) (see above). The results of Strempel's PBT screening

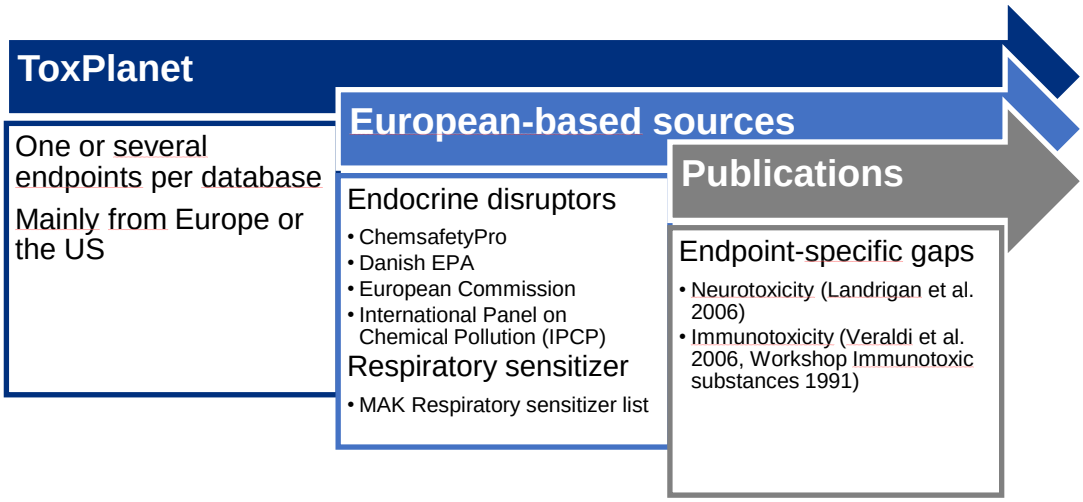
taken from Arp's database generated a single list of 33 substances, all assessed to be potentially PBT by Strempel et al., and assigned as future ("F2") PBT.

A recent report by KWR (2020) 'Persistence of gabapentin, 1H-benzotriazole, diglyme, DTPA, 1,4-dioxane, melamine and urotropin in surface water' tested the biodegradability of the selected substances in surface water, following the OECD 309 guideline. All 7 test substances were calculated to have half-lives exceeding the vP criteria (60 days) of REACH Annex XIII. As all test substances are known to occur in surface water, they were categorised as future ("F1") vPvM.

Human health and endocrine disruptor lists

Substance lists for future human health and endocrine disruptor hazards were compiled by ToxMinds BVBA. The overall approach is illustrated in Figure 1. In the interest of time, a single comprehensive information source was consulted for a primary collation of relevant lists. Screening was done in ToxPlanet, one of the world's largest proprietary toxicological databases. The ListEXPERT™ module of ToxPlanet is an international chemical list data index which includes hundreds of regulatory lists, such as carcinogen lists, list of banned substances, PBTs etc., and as such was the primary source of human health hazard endpoints. Even though many lists include endpoints such as threshold quantities, exposure limits, chemical/physical properties, the focus was to collect substance identifiers and corresponding relevant classifications.

Figure 6-1. Sources of lists used by ToxMinds.



In February 2021, a total of 111 lists from ListEXPERT™ were downloaded and assessed for relevance; each list being initially selected for potential endpoint correspondence based on its name. The second assessment was conducted considering the substance identifiers, classification details, up-to-date details, and most accurate information, leading to the final selection of 40 lists. These 40 lists were endpoint or multi-endpoint specific and were mainly from EU or US organizations. Additional EU sources of information were consulted and included, when appropriate, specifically for the 'endocrine disruptors' (ChemsafetyPro, Danish EPA, European Commission, International Panel on Chemical Pollution (IPCP)) and the 'respiratory sensitiser' (MAK Respiratory sensitizer list) endpoints. A few targeted publications on 'neurotoxicity' and 'immunotoxicity' endpoints completed the exercise.

A total of 51 lists were incorporated into the Master File, corresponding to approximately 13,000 entries.

Expert judgement should be used when interpreting the data in the Master File given the different levels of information reported in the source lists (some were authoritative, some were screening data,

some were current classification, some were evaluations). The lists used, sources, number of substances on each list, and which assignment (C, F1 or F2) of substances to be regulated they were used to identify are given in Table 2. In cases where a list was used for multiple assignments, the highest priority assignment was indicated (C > F1 > F2).

For clarity on the endocrine disruptor endpoints in the 'List of Substances to be Regulated" file, there is currently no formal classification available under EU CLP, however there is discussion the classification could be implemented as with CMR, i.e. Category 1 for confirmed hazard and Category 2 for suspected hazard. The substances referred to in the endocrine disruptor specific columns (EDC HH and EDC ENV) of the list of substances to be regulated are based on published lists. The majority of the lists simply indicate 'suspected' or 'potential' endocrine disruptors without specifying the end target (Human Health and/or the Environment). Therefore, the substances which are listed by European regulation and described as 'identified endocrine disruptors' have been considered as 'current' ("C") and the others 'suspected' and 'potential' have been considered "F1" or "F2". Unfortunately, mapping of these substances and their associated assignments in the list of substances to be regulated to future EDC Category 1 and Category 2 classifications is not viable directly without implementing new rules. Further, if EDCs assigned F1 and F2 in the Master File were directly mapped to EDC Cat 2, there is potential for underestimation of the severity of the hazard, as the assignment of "F1" and "F2" was often due to insufficient testing data thus far, but upon testing many of these substances could be EDC Cat 1.

Specific substance group lists

Lists for specific groups of substances were also collated that were considered less likely to appear on specific lists, but nevertheless were considered as potential candidates for identification as substances to be regulated in the future. One group investigated was PetCo (petroleum and coal stream) substances, which are an important class of UVCBs (substances of unknown or variable composition, complex reaction products or of biological materials) on the EU market. It was considered that some of these substances may be identified as PBT/vPvB based on regulatory activities concerning these substances. In particular, the EU authorities are working towards determining the constituent group of C14-C18 3-ring PAHs as PBT/vPvB (ECHA PBT Expert Group meetings, PetCo 14 meeting, Wassenaar et al., 2021). In addition the substance decahydronaphthalene (CAS Number: 91-17-8) is currently undergoing evaluation as a PBT/vPvB substance as part of REACH Substance Evaluation (SEv) and the Member State Competent Authority of The Netherlands (RIVM) has previously expressed concerns around naphthenic (cyclic) hydrocarbons as another potential group of PBT/vPvB constituents (RIVM, 2019).

Substance lists were collected from Concawe, Lower Olefins and Aromatics (LOA), and Hydrocarbon Solvents Consortium (HCSC). Coal steam substances were excluded due to difficulty in accessing substance lists. However, most of these substances are already identified as CMR. Substances were assigned future ("F1") PBT/vPvB if they were considered likely to contain C14-C18 3-ring polyaromatic hydrocarbons (PAHs) or C10-C20 naphthenics (cyclics). This assessment was performed based on inspection of substance chemical names and descriptions.

The other specific substance group looked at was PFAS (per- and polyfluoroalkyl substances). A list of PFAS was obtained from the OECD (2018) global database of PFAS and these were categorised as "F1" vPvB or vPvM depending on the perfluoroalkyl chain length: substances with a chain length of ≥ C6 were classed as vPvB ("F1"), whereas substances with a chain length of <C6 were classed as vPvM ("F1"). This bright line cut-off was selected based on precedent set by recent ECHA SVHC decisions for PFAS substances, and could be debated. However, the impact is expected to be similar for either outcome as both vPvB and vPvM substances are expected to be SVHC level hazards. N.B. as the list includes polymeric substances (PTFE etc), it should be revisited before using the tool to evaluate these substances, as these substances are considered unlikely to fulfil vPvB criteria.

Tool development and quality assurance

An Excel tool was developed to screen substances against the collected lists and apply the developed rules to ultimately determine the status of a substance. Each collected list exists as separate Excel sheets, with some lists containing multiple tabs if the list assessed multiple hazard endpoints or was used for multiple classifications (C, F1, F2). The tool queries the lists using the VLOOKUP function. All substance identifiers (substance name, EC number and CAS number) are checked against the substance identifiers in each list linked to the tool, however in some lists some substances do not possess all three identifiers. This results in a number of 'hits' for each substance identifier across the lists, which are then consolidated into hits for a substance. The tool then applies the developed rulesets to determine which hazards the substance is considered as fulfilling based on the hits across the lists, and whether these hazards should be assigned "C", "F1", or "F2". Finally, the tool collates the results of this evaluation into an output tab which is of a similar format to the list of substances to be regulated presented in the file 'List of Substances to be Regulated".

Substances for screening in the tool were loaded at the 'front end' and consisted of all REACH registered substances (25,841 substances), approved biocidal active substances (291 substances), all pesticide active substances (excluding banned substances, resulting in 550 substances), and all substances with harmonised CLP classifications (4,617 substances), resulting in a total of 31,285 substances screened.

The 'List of Substances to be Regulated" file specifies where the substance was sourced from (e.g. REACH registered, biocides etc.), along with the substance name, EC number, CAS number, classification categories (total number of C, F1, F2 assignments across the hazards), and assignment for each SVHC, GRA and SoC hazard.

Considering the vast number of formulas, list sheets, list rules, substances and substance identifiers involved, the tool has undergone numerous quality assurance (QA) checks by Ricardo. All 1332 unique formulas within the file have been reviewed, including checking links to external files to ensure data is pulled into the tool correctly. All rulesets for concluding status were also checked for correct functioning. A sample of substances underwent end-to-end calculations to check that the formulas were behaving as intended when written. Finally, the various sheets and overall output for bulk lists of substances was 'sense checked' to ensure that data were pulling through the tool correctly and that classification assignments across the range of hazards and assignments was as expected.

Clean-up and analysis of the List of substances to be regulated

The 'list of substances to be regulated' produced by running the list of substances through the tool was subject to clean-up to remove duplicate substances. An Excel solution was developed to identify substances that had identifiers appearing more than once in the list. Normally at least two duplicate identifiers (i.e. name, CAS, EC) were required to confirm that the substance was indeed a duplicate, in order to avoid mistakenly deleting substances that were not duplicates. However, it was recognised that the chemical name in particular often varies for the same substance. Duplicates identified were checked manually before being removed. In a limited number of cases it was found that the same substance name and CAS number was accompanied by two different EC numbers. In these cases a decision was taken to keep both instances of the substance in the list in order to avoid the risk of substances being missed as a result of the wrong EC number being searched.

The list was analysed to identify the number of substances identified as substances to be regulated across the different hazard categories and C/F1/F2 assignments (see results).

Results

A total of 25,433 unique substances, i.e. duplicated removed, were identified. This is a reduction of 5,852 substances from the 31,285 substances included before the duplicate removal exercise. Of these unique substances, a total of 12,068 were identified as substances to be regulated.

Table 6-9 to Table 6-12 summarise the number of "C", "F1" and "F2" assignments under Substances of Very High Concern (SVHC), General Risk Approach (GRA) and Substances of Concern (SoC). For each of these, the F1 assignment contained the fewest number of substances compared to C and F2 assignments. For SoC, the 8,123 total substances comprised almost entirely of C assignments (8,062 substances), with only 49 and 56 substances assigned F1 and F2, respectively.

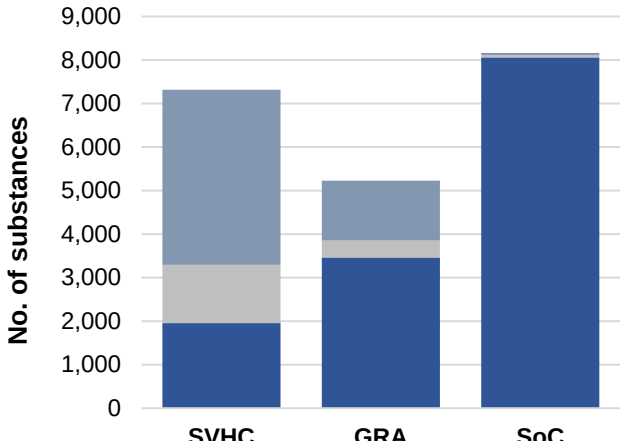


Figure 6-2 Number of substances identified as 'current-C', 'future-F1' or 'future-F2' according to SVHC, GRA or SoC.

Table 6-9 Number of substances identified as 'current' ("C"), 'future' ("F1") or 'future ("F2") according to SVHC, GRA or SoC.

	SVHC	GRA	SoC
Current- C	1944	3462	8062
Future- F1	1352	389	49
Future- F2	4023	1380	56
Any assignment	5907	4601	8123

Table 6-10 Number of substances identified as current (C), future (F1) or future (F2) for each hazard classification under SVHC. Table 6-10to Table 6-12 display the number of substances identified as current (C), future (F1) or future (F2) for each hazard classification. As mentioned above, the vast majority of hazard classifications under SoC are C; only Skin Sens. 1 produces F2 SoCs. For GRA hazards, a greater number of F1 and F2 assignments relative to C assignments are included; only Carc. 2, Resp. Sens. 1 and Neurotox contribute to F2 substances. The number of F1 and F2 assignments relative to C is greater still for SVHCs Table 6-10Table 6-10 Number of substances identified as current (C), future (F1) or future (F2) for each hazard classification under SVHC..

The majority of EDCs identified across all assignments are attributed to endocrine disrupting to human health (1071 substances) rather than to the environment (193 substances). A large number of substances have been identified as current or future SoCs due to their PMT or vPvM properties, 2218 and 3014 substances, respectively. These PMT/vPvM substances are nearly all due to F2 assignments, likely as a result of the screening exercise using the Arp et al. (2017) raw data, which generated lists of 9,032 M/vM substances, and 4,762 P/vP substances.

Table 6-10 Number of substances identified as current (C), future (F1) or future (F2) for each hazard classification under SVHC.

	≥0.1%	*≥0.1%*	*≥0.3%*	*≥0.1%*	*≥0.1%*	*≥0.1%*	*≥0.1%*	*≥0.1%*	*≥0.1%*	*≥0.1%*
	Carc 1A/1B	**Muta 1A/1B**	**Repro 1A/1B**	**EDC HH**	**EDC ENV**	**PBT**	**vPvB**	**PMT**	**vPvM**	**ELoC**
All	1687	1201	1420	1071	193	422	663	2218	3014	25
C	1344	546	727	18	29	44	58	0	0	21
F1	269	655	614	196	164	298	349	39	60	4
F2	74	0	79	857	0	80	256	2179	2954	0

Table 6-11 Number of substances identified as current (C), future (F1) or future (F2) for each hazard classification under GRA.

	≥1 %	*≥1%*	*≥3%*	*≥1%*	*≥0.1 %*	*≥1%*	*≥1%*	*≥10 %*	*≥1%*	*≥10 %*	*≥0.1%*	*≥0.1%*
	Carc 2	**Muta 2**	**Repro 2**	**Resp Sens 1**	**Resp Sens 1A**	**Resp sens 1B**	**STOT RE 1**	**STOT RE 2**	**STOT SE 1**	**STOT SE 2**	**Immuno-tox**	**Neuro-tox**
All	701	599	948	1468	10	66	740	1378	109	102	13	653
C	543	591	906	473	10	29	726	1314	101	98	0	0
F1	41	8	42	247	0	37	14	64	8	4	13	51
F2	117	0	0	748	0	0	0	0	0	0	0	602

Table 6-12 Number of substances identified as current (C), future (F1) or future (F2) for each hazard classification under SoC.

	≥1%	*≥0.1%*	*≥1%*	*≥2.5%*	*≥25%*
	Skin Sens 1	**Skin Sens 1A**	**Skin Sens 1B**	**Aquatic chronic 1**	**Aquatic chronic 2**
All	3165	428	1384	2839	2722
C	3078	423	1379	2830	2717
F1	31	5	5	10	5
F2	56	0	0	0	0

Potential limitations

We would like to point out the following regarding potential limitations of the exercise and its output.

- It should be recognised that this exercise that has been carried out is a high throughput screen of substances. The exercise is designed to provide a credible estimate for a large number of substances of the potential to fulfil criteria to be identified as substances to be regulated for purposes of a broad IA of the CSS, and not necessarily to provide a definitive forecast of individual future hazard classifications. The individual substance conclusions of the exercise should therefore be treated with caution.
- Due to numerous factors, the list as developed has the potential to either over- or under-estimate the actual number of substances to be regulated on the EU market. Potential reasons for over-estimation include use of screening data and suspected, but not yet confirmed, lists to identify substances as SoC (note that assignments of F1 and F2 have been used to account for relative uncertainty). Reasons for underestimation include incomplete lists of substances loaded at the 'front end' (e.g. polymers and low tonnage substances excluded), data availability and potential future testing of substances, and the impact of the use of grouping approaches for future substance evaluation.
- Information from source lists, other than some limited data processing, has been taken at face value and assumed to be accurate. However, it is not possible to rule out inaccuracies in the source information.
- As the exercise was conducted in a high throughput manner, it has not been possible to assess individual substances or groups of substances, other than those specifically identified.
- The tool used to screen substances against lists works on the basis of searching for 'hits' across these lists. Each source list is able to provide a conclusion that a substance is fulfilling a hazard, and the conclusion is assigned C, F1 or F2 depending on whether this is a current or future classification, and on the confidence in that list to determine future classifications. Therefore, there is no cross-checking between lists in the determination of SoC hazards. The only such rule is an order of precedence of C > F1 > F2 in the final SoC determination. It should therefore be recognised that the tool is not able to 'deselect' a SoC hazard based on source list information. For example, if a substance was indicated SoC for Carc. 1A/1B based on RISCTOX but had been concluded in a REACH CoRAP evaluation to not be a Carc. 1A/1B, the substance would still be indicated F2 for Carc. 1A/1B in the output.
- Substance classification data has been pulled directly from the ECHA website. This includes harmonised classifications and REACH registered classifications. In the case of REACH registered classifications, substances which have multiple instances of CLP classifications in the dossier (for example reflecting different impurity profiles), will pull all classifications corresponding to these impurity profiles. An example of this is ethanol, which has different classification sets depending on the impurity profile. As a result, ethanol is indicated as a "C" Carc. 1A/1B in the SoC list. Although these instances are expected to be limited, there is unfortunately no way to resolve this according to the current methodology.
- It is recognised that the list of 31,285 substances used in the screening (i.e. REACH registered substances, biocides, PPP active substances, CLH substances), whilst being very large, is not a comprehensive list of all substances on the EU market. Notably, those substances that may not be included in the tool include:
    - Polymers (including some surfactants)
    - REACH Annex IV and V exempted substances
    - Individual constituents of complex/multi-constituent substances
    - Industrial chemicals marketed at < 1 tonne/annum
    - Nonetheless, it is felt that this list is sufficient to capture the bulk of substances in the database that are relevant to the EU market. The substances that are excluded from

these searches are also considered unlikely to be present in the database due to an overall lack of information on these substances.

- UVCB substances are considered potentially less likely to appear on source lists used in the tool. They may therefore be underrepresented in the list of future (F1 and F2) SoCs. In order to provide a more representative analysis of UVCBs a specific investigation would be required for individual types of substances, which was not possible within the scope of this project. As an exception, it was possible to make some specific assessment of the PetCo and PFAS substances for their PBT/vPvB and vPvM/vPvB properties, respectively.

A3 Detailed Overview of Sources for List of Substances to be Regulated

A3.1 Descriptions of list sources

Index

43. UBA (2020) “Red” substances list
44. UBA (2018) $P_{aq}MT$, $P_{aq}M$ with suspected T, and suspected $P_{aq}MT$ substances list
45. UBA (2019) PMT/vPvM REACH registered substances reported in drinking water or groundwater list
46. KWR (2020) P assessments of 7 substances found in surface water
47. Global database of PFAS list
48. PetCo potential PBT substances list
49. eChemPortal screening lists
50. Jon Arnot BCF/BAF database
51. Jon Arnot BMF database

1. ListEXPERT from Toxplanet

Toxplanet is one of the world’s largest toxicological databases, encompassing more than 340 individual databases from leading international sources and covering nearly 1 million unique compounds. The ListEXPERT™ database from Toxplanet is an international chemical list data index including extensive information on hundreds of thousands of chemicals from regulatory and advisory lists worldwide. ListEXPERT™ includes chemical inventories, carcinogen lists, exposure limit lists, list of banned substances, lists of hazardous chemicals, toxics and PBTs (persistent, bioaccumulative and toxic substances). In addition to list data, actual source documents are included when available. Many lists in ListEXPERT™ also include other endpoints such as classification, threshold quantities, exposure limits, and chemical and physical properties. When new information from any of the content sources becomes available, this is automatically processed in Toxplanet and becomes accessible within 72 hours. Toxplanet and ListExpert™ can be accessed at https://toxplanet.com/.

2. Boyes – Neurotoxicants

Information on potential neurotoxic properties of selected substances can be found in the book chapter: ‘Neurotoxicology and Behavior’ by Boyes et al. (2001). In the books’ chapter the author describes the major classes of environmental and occupational neurotoxicants such as metals, insecticides, and organic solvents. It also describes some other compounds that produce neurotoxic effects but do not fall within these three categories. The author also described in detail about neurotoxic effect along with mechanism of neurotoxicity for some of the listed chemicals. This article can be assessed at https://onlinelibrary.wiley.com/doi/abs/10.1002/0471435139.tox025.pub2
The corresponding source of information is related to a third-party publication and has been considered therefore as ‘F2’.

3. CalEPA - Cancer Potency Factor Database

The California Environmental Protection Agency (CalEPA) Office of Environmental Health Hazard and Assessment (OEHHA) is responsible for developing and distributing toxicological and medical information needed to protect public health. For the selection of cancer potency factors (CPF), CalEPA has established a database providing summaries of values originally developed for other CalEPA programs or by the United States Environmental Protection Agency (US EPA). They are reviewed for accuracy, reliance on up-to-date data and methodology. Values found appropriate are adopted after public and peer review rather than devoting the resources necessary for a full de novo assessment. The CPF included in the Technical Support Document (TSD) for Cancer Potency Factors are from the following sources:

- Toxic Air Contaminant documents
- Standard Proposition 65 documents
- U.S.EPA Integrated Risk Information Systems (Office of Health and Environmental Assessment, U.S.EPA)
- Expedited Proposition 65 documents
- Other OEHHA assessments, for example for the drinking water program.

The CalEPA database is available at https://oehha.ca.gov/media/downloads/crnr/appendixb.pdf. All Cal/EPA program documents undergo a process of public comment and scientific peer review prior to adoption. The database has consequently been considered 'F1'.

4. ChemsafetyPro - UN List of Identified EDCs

ChemsafetyPro is a database created by a group of chemical regulatory experts. ChemsafetyPro includes a list of substances published by the United Nations (UN) that, having gone through at least one 'thorough scientific assessment', have been identified as endocrine disrupting chemicals (EDCs). The aim of the list is to give a global overview of the initiatives, policies and scientific knowledge around identifying endocrine disrupting chemicals. ChemsafetyPro is available at https://www.chemsafetypro.com/Topics/Restriction/UN_list_identified_endocrine_disrupting_chemicals_EDCs.html.
The ChemsafetyPro has been considered as 'F2'.

5. Colborn List - Widespread Pollutants with Endocrine-Disrupting Effects

In her book 'Our stolen future' Dr. Theo Colborn described the health and environmental threats created by man-made chemical contaminants that interfere with hormones in humans and wildlife. 'Our Stolen Future' summarizes a series of well-studied examples where people have been affected by endocrine disrupting chemicals. The book also provides the list of endocrine disrupting effects.
The Colborn list is available at http://www.ourstolenfuture.com/basics/chemlist.htm.
The corresponding source of information is related to a third-party publication and has been considered therefore as 'F2'.

6. Danish EPA – Potential Endocrine Disruptors

The Danish Centre on Endocrine Disruptors (CeHoS) is an interdisciplinary scientific network funded by the Danish Environmental Protection Agency (EPA). The main purpose of the CeHoS is to build and gather new knowledge on endocrine disrupting chemicals.
On their website, Danish EPA refer to a list published by the European Commission as part of their strategy for endocrine disruptors. The list is based on the proposals of various organisations and countries for suspected endocrine disruptors. The proposals were compared and a collective EU list of over 432 candidate substances was established, which were to be studied further for endocrine-disrupting properties. The list is available at https://eng.mst.dk/chemicals/chemicals-in-products/focus-on-specific-substances/endocrine-disruptors/the-eu-list-of-potential-endocrine-disruptors/
The Danish EPA list has been considered as 'F2'.

7. European Commission - Endocrine Disruptors

BKH Consulting Engineers (Delft, the Netherlands) was commissioned by the European Commission in 1999 to conduct a study on endocrine disruption focusing on man-made chemicals. The priority list was to be established in two phases, first an independent review of evidence of endocrine disrupting effects and human/wildlife exposure and second a priority-setting exercise in consultations with stakeholders and the Commission Scientific Committees.

- Annex 1 corresponds to the "Candidate list of 553 substances",
- Annex 13 corresponds to the "List of 146 substances with endocrine disruption categorizations prepared in the Expert meeting",
- Annex 15 corresponds to the "List of 66 Category 1 substances with categorisation high, medium or low exposure concern".

The lists are available at https://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm
All substances mentioned under the European Commission have been considered as 'F1'.

8. European Commission – Potential EDCs in Cosmetics

On 7 November 2018, the European Commission adopted the review of Regulation (EC) No 1223/2009 on cosmetic products regarding substances with endocrine-disrupting properties. In the report, the EC committed to establishing a priority list of potential endocrine disruptors not already covered by the bans in the cosmetics regulation by the end of March 2019 for risk assessment. The starting point for this priority list was the result of the screening study that was conducted to support the impact assessment in the field of plant protection products and biocides.

A final list of 28 substances was consolidated. Internal discussions were carried out to determine if any of these 28 substances were being assessed under REACH for endocrine disruptor concerns. Additionally, an informal consultation with the SCCS helped to prioritise the substances based on scientific evidence/literature. As a result of these discussions, the list of 28 substances was split into the 2 following groups:

- Group A consists of 14 substances that should be treated with higher priority for assessment as they are undergoing substance evaluation (SEV) under REACH for ED concerns or the SEV has already confirmed ED concerns.
- Group B consists of 14 substances where either no SEV has been initiated or the outcome of the SEV is of an environmental ED concern and not a human health one. Group B also contains substances that have recently been evaluated by the SCCS and found safe, and/or substances that have been recently classified as CMRs under CLP where corresponding risk assessment/management measures are in place to prohibit/restrict their use in cosmetic products.

The lists are available at https://ec.europa.eu/growth/content/call-data-ingredients-potential-endocrine-disrupting-properties-used-cosmetic-products_en

The two groups of the European Commission have been considered differently: Group A has been considered as 'current;, while Groupe B has been considered as 'F1'.

9. European Union Endocrine Disruptor Lists

Within the EU, five national competent authorities have joined forces to compile and maintain three lists of endocrine disrupting chemicals on a dedicated website:

- List I: Substances identified as endocrine disruptors at EU level. This list contains substances that have undergone the full evaluation process for endocrine disruption as regulated in the EU under the Plant Protection Products Regulation, the Biocidal Products Regulation or REACH (the Candidate- and Authorisation Lists).
- List II: Substances under evaluation for endocrine disruption under an EU legislation. This list contains substances that are currently under evaluation in an EU legislative process due to explicit concerns for possible endocrine disrupting properties.
- List III: Substances considered, by the evaluating National Authority, to have endocrine disrupting properties. This list contains substances for which a participating national authority has evaluated endocrine disrupting properties based on scientific evidence. However, it is important to note that these substances have not yet been confirmed to be endocrine disruptors.

The EU Endocrine Disruptor Lists are available at https://edlists.org/. List I of the EU Endocrine Disruptor Lists has been considered as 'current', while Lists II and III have been considered as 'F1'.

10. German MAK Commission - Respiratory allergens

The German Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (MAK Commission) report 56 evaluates and publishes recommendations for health-based limit values at the workplace. The MAK collection contains the comprehensive documentations and corresponding methods of determination for the MAK values, classifications and notations. Assessment values in biological material and biomonitoring methods are also reported. Within the documentations and method descriptions, the Commission, with the support of additional experts and the Scientific Secretariat, summarizes all the available toxicological information on a substance, its mechanisms of action and evaluations relevant to the workplace exposure. The list is available at https://series.publisso.de/en/pgseries/overview/mak/lmbv/curIssue.

The information provided in report 56 has been considered as 'F1'.

11. Grandjean & Landrigran (2006) - - Known neurotoxicants in man

Information on known neurotoxicants can be found in the publication 'Developmental neurotoxicity of industrial chemicals' by Grandjean & Landrigan (2006). To identify environmental chemicals that are toxic to the human brain, a search was conducted by the authors in the hazardous substances data bank of the US National Library of Medicine, where substances are listed with their adverse effects in human beings. The completeness of this list was checked against other data sources and with a previous review of published data for clinical toxicity. The substance names were used for

searches of published data for developmental neurotoxicity. The few known chemicals causing neurodevelopmental abnormalities are highlighted in the panel. The publication can be found at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(06)69665-7/fulltext#articleInformation. The source has been considered as 'F2'.

12. International Panel on Chemical Pollution (IPCP) – Lists of EDCs

The International Panel on Chemical Pollution (IPCP) reviewed existing, publicly accessible lists created by various stakeholders (governments, industry, civil society and academia) and consolidated them into a single database. This consolidated database contains more than 1,000 chemicals compiled from over fifteen lists. Many of the compiled lists include a brief description of a chemical's possible applications, and some have information on the toxicity to humans or wildlife with references to scientific literature.

According to the purpose and actual content, the panel categorised each list into four groups in four tables

along with explanatory notes. Lists in Table 1 reflect chemicals that are labelled as EDCs, or suggested as potential EDCs, by individual organisations. Their Table 2 includes lists of chemicals where evaluation is ongoing to identify whether they shall be labelled as EDCs or potential EDCs. Lists included in Table 3 are created to cover a wide range of chemicals and do not explicitly identify chemicals as EDCs or potential EDCs. They do, however, include chemicals that have been suggested as EDCs or potential EDCs by other organizations. Table 4 includes knowledge bases and databases with focus on endocrine disruption including details such as experimental results, modelling data, and completed studies on EDCs. The list is available at https://wedocs.unep.org/handle/20.500.11822/12218. The IPCP link can be found at https://www.ipcp.ch/activities/endocrine-disrupting-chemicals. The lists of substances have been allocated to the two categories 'F1' and 'F2' based on the different tables.

13. NIOSH - Carcinogen List

The National Institute for Occupational Safety and Health (NIOSH) is the United States federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. The list of substances NIOSH considers to be potential occupational carcinogens are presented in the below link. Some of the potential carcinogens listed in this index may be re-evaluated by NIOSH as new data become available and the NIOSH recommendations on these carcinogens may change. The list is available at https://www.cdc.gov/niosh/topics/cancer/npotocca.html. This source of information is located outside the European Union and has been considered as 'F2'.

14. NTP - 14th Report on Carcinogens (RoC)

The National Toxicology Program (NTP) is an inter-agency program run by the United States Department of Health and Human Services. The NTP Report on Carcinogens (RoC) is a scientific and public health document that identifies and discusses agents, substances, mixtures, or exposure circumstances that may pose a cancer hazard to humans. To prepare the 14th RoC, NTP followed a four-part process using established listing criteria. This process included input from the NTP Board of Scientific Counsellors and the NTP Executive Committee, which includes the heads (or their designees) from several HHS agencies (FDA, National Cancer Institute, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, National Institute of Environmental Health Sciences, and NIOSH), as well as other federal agencies (Consumer Product Safety Commission, Department of Defense, EPA, and OSHA).

The RoC is a cumulative report. It includes information on the newly reviewed substances, as well as those listed in previous editions. Substances are categorised as:

- Known to be a human carcinogen
- Reasonably anticipated to be a human carcinogen
- Substances under evaluation

The two first lists are available at https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf. Substances under evaluation can be found at https://ntp.niehs.nih.gov/whatwestudy/assessments/cancer/ongoing/index.html. The substances identified as 'Known to be a Human Carcinogen' have been considered as 'F1'. The substances identified as 'Reasonably Anticipated to be a Human Carcinogen' and 'Under evaluation' have been considered as 'future potential.

15. NTP - Completed RoC Evaluations

The Report on Carcinogens (RoC) is a congressionally mandated, science-based, public health document prepared by the National Toxicology Program (NTP). Substances listed in the RoC were evaluated for cancer hazards using a formal process and established listing criteria. This list includes categories such as:

- Substances listed in the Report on Carcinogens.
- Substances reviewed by NTP but not listed in the Report on Carcinogens.
- Substances previously listed which have been removed from the report.

For each substance, information related to the cancer hazard evaluation is provided, including scientific review document, substance profile, meetings and reports related to the review of the scientific document and public comments. The list is available at Completed RoC Evaluations (nih.gov). The substances compiled under the completed RoC Evaluations have been considered as 'F1' or 'F2' depending on their cancer hazard evaluations.

16. RISCTOX

RISCTOX is a database of hazardous substances developed to provide information about health and environmental risks caused by chemicals contained in products generally used or handled by companies. This database has been commissioned by the European Trade Union Institute (ETUI) and financed by the European Commission. This database provides the list of various reproductive toxicant, endocrine disrupters, sensitizers and neurotoxicants. The complete list of substances can be accessed at RISCTOX: Toxic and hazardous substances database (istas.net). The substances within the RISCTOX database have been considered 'F2'.

17. Safe Work Australia - Model Work Health and Safety Regulation

The Australian Work Health and Safety (WHS) Regulation, dated 1st January 2021, released by Safe Work Australia and published by the Parliamentary Counsel's Committee, contains a list (Schedule 10) of prohibited carcinogens that can only be used where the WHS regulator has authorised the use for genuine research or analysis. The WHS Regulation is available at https://www.safeworkaustralia.gov.au/sites/default/files/2021-01/Model-WHS-Regulations-1January2021.pdf. The Safe Work Australia representing substances with formal evaluation list has been considered 'F1'.

18. TEDX - List of Potential EDs

TEDX is a science based, non-profit research institute. The TEDX List of Potential Endocrine Disruptors identifies chemicals that have shown evidence of endocrine disruption in scientific research. TEDX researchers evaluates chemicals by searching the publicly available scientific literature and identifying peer-reviewed research showing effects on endocrine signalling. TEDX provides a master list of potential endocrine disruptors, defined as chemicals with at least one study demonstrating endocrine disrupting properties. The list is available at https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/search-the-tedx-list#sname=&searchfor=any&sortby=chemname&action=search&searchcats=all&sortby=chemname. As the source of information is located outside the European Union, the TEDX database have been considered 'F2'.

19. US AOEC Respiratory Sensitizer List

The US Association of Occupational and Environmental Clinics (AOEC) developed criteria to review the peer-reviewed medical literature published in English. Substances designated either as sensitizing agents or irritants were reviewed by a board-certified internist/pulmonologist/occupational medicine specialist from 2002 to 2007 and by a board-certified internist/occupational medicine physician from 2008 onwards.

The original list of substances associated with new onset work-related asthma was derived from the tables of a textbook on work-related asthma (Chan-Teung et al., 1999). After 13 years of review, there are 327 substances designated as asthma agents on the AOEC list. The listing is based on peer-reviewed criteria and updated twice a year. The AOEC Respiratory Sensitizer list can be accessed at http://www.aoecdata.org/.

The AOEC Respiratory Sensitizer List is composed of peer-reviewed medical literatures and has been consequently considered 'F1'.

20. US ATSDR Database

The Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency of the US Department of Health and Human Services. The agency maintains a Toxic Substances Portal that compiles all the Agency's toxicology information and allows users to search by chemical. This database covers toxicity information on all end points, it provides useful information about toxicological profiles substance and Information about contaminants found at hazardous waste sites. The ATSDR database is available at https://wwwn.cdc.gov/TSP/index.aspx. The database has been considered 'F1'.

21. US Congress – Workshop on Immunotoxic Substances

A workshop by the US Congress, Office of Technology Assessment, describes some of the research that has been done on substances or classes of substances to determine whether they can suppress the immune system or cause hypersensitivity or autoimmune reactions. Specific note is made of the origin (animal or human) of the data. The workshop also provides the list of 47 chemical which are either known or suspected immunosuppressants. The list is available at https://www.princeton.edu/~ota/disk1/1991/9124/9124.PDF.
The information provided in this workshop have been considered 'potential future'.

22. US EPA - Endocrine Disruptor Screening Program (EDSP)

The United States Environmental Protection Agency's (US EPA) Endocrine Disruptor Screening Program (EDSP) was established in the late 1990s. The EPA devised a two-tiered testing program to assess the approximately 10,000 chemicals slated to be screened for endocrine disruption. The Tier 1 screening tests consist of five *in vitro* and six *in vivo* tests. Any chemicals that display possible impacts may be further evaluated with additional animal testing in Tier 2, which is designed to confirm the adverse endocrine effects on animals and determine at what dose the chemical affects the endocrine system. The EPA has released its reviews of the Tier 1 screening assay results for the first 52 pesticide chemicals (active and inert ingredients) in the Endocrine Disruptor Screening Program. The lists are available at https://www.epa.gov/endocrine-disruption/overview-first-list-chemicals-tier-1-screening-under-endocrine-disruptor or https://www.epa.gov/endocrine-disruption/overview-second-list-chemicals-tier-1-screening-under-endocrine-disruptor
Both Tiered Screening list have been considered 'F2'.

23. US EPA - IRIS - Weight of Evidence of Carcinogenicity

The primary source of the weight of evidence (WoE) for cancer data is US EPA's Integrated Risk Information System (IRIS). IRIS includes information on EPA evaluations of chemical toxicity for both cancer and noncancer effects of chemicals. IRIS provides both background information on the studies used to develop the toxicity evaluations and the numerical toxicity values used by EPA to characterize risks from these chemicals. The peer-review process involves literature review and evaluation of a chemical by individual EPA program offices and intra-agency work groups before inclusion in IRIS. IRIS is available at http://www.epa.gov/iris/. The list has been considered 'F2'.

24. US EPA – List of Chemicals Evaluated for Carcinogenic Potential

The US EPA list of Chemicals Evaluated for Carcinogenic Potential provides an overview of pesticide chemicals evaluated for carcinogenic potential by EPA's pesticide program through September 2018. The evaluation of many of these chemicals is an ongoing process; therefore, the information in this list may be subject to change as new and/or additional data are submitted to EPA.
The cancer assessment review committee recommends a "descriptor" (e.g., likely to be carcinogenic to humans, not likely to be carcinogenic to humans, suggestive evidence of carcinogenic potential) to convey the cancer hazard potential of the compound. The list is available at https://apublica.org/wp-content/uploads/2020/05/chemicals-evaluated.pdf. The list has been considered 'F2'.

25. US OSHA – Carcinogens List

The US Occupational Safety & Health Administration (OSHA) compiles an occupational chemical database as a reference for the occupational safety and health community. It compiles information from several government agencies and organizations. In 2018, OSHA published a list of 13 chemicals which can be potential occupational carcinogens. The list is available at

https://www.cdc.gov/niosh/npg/nengapdxb.html. The substances compiled by OSHA have been considered 'F1'.

26. Veraldi et al. (2006) - Immunotoxicity evaluation of 20 substances

A study conducted by Veraldi et al. (2006) in 'Immunotoxic effects of chemicals: A matrix for occupational and environmental epidemiological studies' evaluates the immunotoxicity of 20 substances used widely in work environments. A total 321 studies were reviewed. References for each study and specific to the organizations that recommend or mention the use of these tests, and, when considered, the immunotoxicity of chemicals. The list of 20 chemicals can be found at https://pubmed.ncbi.nlm.nih.gov/17036363/ and is considered 'F2'.

27. Harmonised classification and labelling list

Harmonised classification and labelling data (CLP Annex VI) were pulled for each relevant hazard classification under the Globally Harmonised System, as opposed to the Seveso Directive. The lists can be found for each hazard through this link: https://echa.europa.eu/advanced-search-for-chemicals. The generated substance lists for each relevant hazard classification contributed to the identification of current substances of concern.

28. REACH registered classification and labelling list

REACH registration classification and labelling data were pulled for each relevant hazard classification under the Globally Harmonised System (GHS). The lists can be found for each hazard through this link: https://echa.europa.eu/advanced-search-for-chemicals. These lists were used to identify current substances of concern.

29. Candidate list of SVHC for authorisation

ECHA's candidate list of Substances of Very High Concern (SVHC) for authorisation, published in accordance with Article 59(10) of the REACH Regulation, was categorised based on each of the 211 substance's reason for inclusion in the list (Article 57a-e). The list is available at https://echa.europa.eu/candidate-list-table. All human health and environmental classifications were used to identify 'current' substances of concern.

30. Substance evaluation/CoRAP list

ECHA's Community rolling action plan (CoRAP) lists substances that have or will soon be evaluated by Member States due to the identification of specific concerns that the substance could pose a risk to human health and/or the environment. The list includes substance identification parameters, the evaluating Member State, the year of evaluation, the reason(s) for inclusion on the list, and links to additional documents regarding the substance evaluation. The list is available at https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table.

From the export, substances with evaluations that were withdrawn or concluded were filtered out. Those remaining were filtered for their initial grounds for concern, e.g. CMR, suspected PBT/vPvB, potential endocrine disruptor, sensitiser etc. In addition, hazard classifications proposed by the evaluating Member State were taken from the substance evaluation conclusion reports for concluded substances. These concluded hazards were treated as 'current', while the potential/suspected hazards were treated as 'F1'. In cases where the concern didn't equate to a classification given in the final spreadsheet, the generic or higher hazard category was selected, for example 'potential ED' in the CoRAP list mapped to 'EDC HH' and 'EDC ENV' in the final list.

31. ED assessment list

ECHA's endocrine disruptor (ED) assessment list comprises substances for which an evaluation is being developed or has been concluded by ECHA and Member State Competent Authorities (MSCAs) due to their suspected endocrine disrupting properties. This includes substances under REACH or the Biocidal Products Regulation that the ED Expert Group have discussed. The list is available at https://echa.europa.eu/ed-assessment.

This list provides substances that have been concluded as endocrine disruptors to the environment, endocrine disruptors to human health, or still under assessment due to endocrine disruptor concern. Those substances for which the ED assessment has been concluded were incorporated as 'current' under the EDC ENV or EDC HH headings in the table, whereas those substances not concluded but an ED concern still exists were incorporated as 'F1' EDC ENV/HH.

32. PBT assessment list

ECHA's PBT assessment list provides substances being evaluated for persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB) properties by ECHA and the EU MSCAs. As in the ED assessment list, these are substances under REACH or the Biocidal Products Regulation that have been brought for attention in the relevant Expert Group, in this case the PBT Expert Group. The list is available at https://echa.europa.eu/pbt.
Substances were filtered depending on the outcome of their PBT assessment conclusion: concluded PBT, concluded vPvB, or not concluded but a PBT concern remains. Those with no PBT concern specified were grouped with the 'not concluded, PBT concern' substances, as the substances are still under assessment as PBT according to ECHA. Concluded substances were mapped as 'current' PBT or vPvB substances (dependent on the conclusion), whereas those not yet concluded were mapped as 'F1' PBT and vPvB, or equivalent level of concern.

33. Substances subject to POPs regulation list

ECHA's list of substances subject to POPs regulation details substances currently (as of February 2021) listed in the following annexes to the POPs regulation: Annex I (substances subject to prohibition (with specific exemptions) on manufacturing, placing on the market and use), Annex II (substances subject restriction on manufacturing, placing on the market and use), Annex III (substances subject to release reduction provisions), and Annex IV (substances subject to waste management provisions). The list is available at https://echa.europa.eu/list-of-substances-subject-to-pops-regulation. The list comprised 86 substances subject to POPs regulation. No filtering of data needed to be performed; all 86 substances were mapped as 'current' PBT/vPvB.

34. Previous biocidal active substance potential candidates for substitution list

This is an ECHA list of 42 biocidal active substances which were potential candidates for substitution during previous consultations, all of which have now been concluded. The export includes which of the substitution criteria set out in Article 10(1) of the Biocidal Products Regulation (BPR) is met for each active substance. From these criteria, classifications such as PMT, vPvM, ED, Carc. 1A or 1B, Repro. 2 etc. could be used to categorise the substances.

35. RMOA list

ECHA's regulatory management option analysis (RMOA) list details substances for which ECHA or Member States are preparing or have completed an RMOA since February 2013. The evaluating body decides whether regulatory action is warranted for the substance based on its hazard-related concern, and if so, what the most appropriate action is. The export includes the concern, the status, the outcome of the RMOA, and any follow-up proposed (e.g. restriction, listing as a SVHC, harmonised classification and labelling etc.). The list is available at https://echa.europa.eu/rmoa.
Substances for which there was no need to initiate further regulatory risk management at this time were excluded. Those substances whose RMOA was on hold, under development or concluded as appropriate to initiate regulatory action were filtered based on concern relevant to this exercise; exposure, widespread use, and aggregated tonnage concerns were not included.

36. Registry of CLH intentions until outcome list

ECHA's registry of classification and labelling (CLH) intentions until outcome list includes proposed new/revised harmonised classifications received by ECHA from importers, manufacturers, downstream users or MSCAs. The export includes the status of the proposal, from intention to opinion adopted by the Committee for Risk Assessment (RAC). The list is available at https://echa.europa.eu/registry-of-clh-intentions-until-outcome.

Substances with the 'withdrawn' or 'opinion adopted' status were excluded, leaving those substances with consultation, intention, opinion development and submitted statuses. Substances were filtered based on the proposed harmonised classification by the dossier submitter. These intended classifications were then mapped as 'F1'.

37. Substances proposed as POPs list

This is a list generated by ECHA to display substances proposed by the Commission and other parties for potential inclusion in the Stockholm Convention, comprising 50 substances at time of export. For each substance, the dates for each step in the process are given, from the consultation

of the draft risk proposal, to the adoption of the risk profile or risk management evaluation by the POP Review Committee, to inclusion in the Stockholm Convention and POPs regulation. The list is available at https://echa.europa.eu/list-of-substances-proposed-as-pops.

This list includes substances for which a risk profile is under development, a proposal is under preparation, a risk management evaluation is under development, or those recommended for listing under the Stockholm Convention. Three substances that are already listed under the Stockholm Convention/POPs regulation were removed, as these substances are captured in the 'substances subject to POPs regulation' list above. The remaining 47 substances were mapped as 'F1' PBT/vPvB.

38. Pesticide active substance candidates for substitution list

This European Commission list provides pesticide active substances identified as candidates for substitution based on properties of concern, such as PBT or other health endpoints. Relevant endpoints/classifications were pulled out as separate lists. Repro 1A or 1B and vPvB classifications were mapped as 'current', while PMT and vPvM were mapped as 'F1'. Any active substances listed as endocrine disrupting were mapped as 'F1' EDC HH and EDC ENV.

39. SIN list

The SIN (Substitute It Now) list from ChemSec is a database of substances that fulfil ECHA's SVHC criteria. The export includes hazard class and category codes for each substance, as well as the reason for the substance's inclusion on the list, amongst other information. The list can be accessed via https://sinlist.chemsec.org/. As with the treatment of the candidate list, the 991 substances on the SIN list were categorised according to the reason for inclusion on the list, e.g. ED, reprotoxic etc. These classifications were used to identify future ("F1") substances of concern.

40. Arp et al. (2017) P/vP and M/vM screening list

The Arp et al. (2017) paper "Ranking REACH registered neutral, ionizable and ionic organic chemicals based on their aquatic persistency and mobility" screened REACH chemicals as persistent and mobile organic compounds (PMOCs) based on publicly available experimental and QSAR data. The supplementary material (part 2 of 2) to this paper includes 5,155 REACH organic compounds, their hydrolysis products, and their associated endpoint values relevant to PMOC score derivation, e.g. pKa, logKow, logDow, logKoc, logDoc, water solubility etc.

While the supplementary material does not include substances registered since 2014, or UVCBs, the raw data was used to flag substances as P/vP and M/vM according to the criteria proposed by UBA (slightly different to the criteria used by Arp et al.). Substances were assessed as M/vM if the minimum logKow/Dow was less than 4.5 or logKoc less than 4, and as P/vP if they had a biodegradation score of 3 or 4. Any substances flagged as both P/vP and M/vM by this study were identified as 'F2' PMT and vPvM.

41. Strempel et al. (2012) PBT screening of REACH registered chemicals (up to 2012)

Estimated P, B and T property screening data from the paper 'Screening for PBT Chemicals among the "Existing" and "New" Chemicals of the EU' by Strempel et al. (2012) was included in part 2 of the Supplementary Material from Arp et al. (2017) (see above). The results of Strempel's PBT screening taken from Arp's database generated a single list of 33 substances all assessed to be potentially PBT by Strempel et al., and classed as 'F1' PBT in our file.

42. UBA (2020) "Iceberg" substances list

The UBA (German Environment Agency) report 'PBT - Quo vadis? Examination and further development of the PBT assessment approach for identification of environmental SVHC' investigated the PBT concept, which included compiling P and B estimations for "iceberg" substances. For this task, substances detected in environmental monitoring studies in remote areas were assessed for their P and B properties using EpiSuite estimations: non-linear model prediction (BIOWIN 2), ultimate biodegradation (BIOWIN 3), MITI non-linear model prediction (BIOWIN 6), bioconcentration factor (BCFBAF), logKow (KOWWIN), and logKoa (KOAWIN). 11 substances within the "Iceberg" list were assessed to be potentially PB, PvB, B and vB. Despite the different categories, this source was treated as a single list used to identify 'F1' PBT and vPvB substances.

43. UBA (2020) "Red" substances list

This list is part of the same UBA report as above: 'PBT - Quo vadis? Examination and further development of the PBT assessment approach for identification of environmental SVHC'. In addition to finding potentially PB, PvB, B and vB substances using monitoring data and EpiSuite estimations, the study included an evaluation of existing PBT/vPvB classifications.

UBA analysed 53 previously suspected PBT/vPvB substances which have been concluded to be non PBT/vPvB by the PBT Expert Group. Of these 53 substances, 23 were "green" (non PBT decision is well supported), 22 were "orange" (some indication for P, B, or T properties but insufficient data for a final PBT classification), and 8 were "red" (strong indication that a PBT classification could be concluded). These 8 "red" substances were included as a list to identify 'F1' PBT substances.

44. UBA (2018) P_{aq}MT, P_{aq}M with suspected T, and suspected P_{aq}MT substances list

This list was taken from the UBA report 'Assessment of persistence, mobility and toxicity (PMT) of 167 REACH registered substances'. The 167 substances were selected from the PROMOTE research project (n = 156) and from a previous UBA research project (Kalberlah et al., 2014) (n = 11). All information, including validated QSARs, was evaluated in weight-of-evidence approach using expert judgement.

This evaluation produced 3 lists we could use: 8 substances assessed as P_{aq}MT, 21 as P_{aq}M with suspected T, and 105 as suspected P_{aq}MT. All 134 substances were used to identify future substances of concern. PMT substances were mapped as 'F1' PMT, while the PM with suspected T and suspected PMT substances were mapped as 'F2' PMT.

45. UBA (2019) PMT/vPvM REACH registered substances reported in drinking water or groundwater list

This list was taken from the UBA report 'Protecting the sources of our drinking water. The criteria for identifying Persistent, Mobile, and Toxic (PMT) substances and very Persistent, and very Mobile (vPvM) substances under EU REACH Regulation'.

A PMT/vPvM assessment was performed for 142 REACH registered substances (as of May 2017) that have been reported in at least one study as detected in groundwater or drinking water, modified from Arp & Hale (2019). 70 substances were assessed to be potential PMT/vPvM (mapped as 'F2' PMT or 'F2' vPvM), 14 as PMT, 1 as vPvM and 1 as PMT/vPvM (mapped as 'F1' PMT, vPvM or PMT/vPvM).

46. KWR (2020) P assessments of 7 substances found in surface water

A recent report by KWR 'Persistence of gabapentin, 1H-benzotriazole, diglyme, DTPA, 1,4-dioxane, melamine and urotropin in surface water' tested the biodegradability of the selected substances in surface water, following the OECD 309 guideline. All 7 test substances were calculated to have half-lives of at least 67.6 days, exceeding the vP criteria (60 days) of the REACH regulation. As all test substances are known to occur in surface water, they were categorised as 'F1' vPvM in the spreadsheet.

47. Global database of PFAS list

The Organisation for Economic Co-operation and Development (OECD) is an international, intergovernmental economic organisation. Their 'portal on per and poly fluorinated chemicals' includes a global database of PFAS, discussed in the 2018 report 'Toward a new comprehensive global database of per-and polyfluoroalkyl substances (PFASs): summary report on updating the OECD 2007 list of per-and polyfluoroalkyl substances (PFASs).' The database contains 4730 new PFAS, including several new groups of PFASs that fulfil the common definition of , but are not commonly regarded as, PFAS. The database can be downloaded from http://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/. This list was used to identify 'F1' vPvB and vPvM substances of concern; this vB vs vM decision was dependent on the length of the fully fluorinated carbon chain.

47. PetCo potential PBT substances list

A list of potentially PBT PetCo (petroleum and coal stream) substances was produced based on a number of sources. Based on substance names and descriptions, relevant PetCo substances were

identified from Concawe's Inventory of Petroleum Substances (version 15, published in 2020) and Relevant Lower Olefins/Aromatics Consortium (LOA), i.e. if they were considered likely to contain C14-C18 3-ring polyaromatic hydrocarbons (PAHs) or C10-C20 naphthenics (cyclics). For hydrocarbon solvents, a database was used from the Hydrocarbon Solvents REACH Consortium (HCSC). Hydrocarbon solvents in categories 3, 4, 8 and 9 were screened, and those with a carbon chain length of C10-C20 which contained cyclics were added to the list. This combined list was used to identify 'F1' PBT/vPvB substances**.**

48. eChemPortal screening lists

The eChemPortal, first launched in 2007, is a free, publicly accessible information source developed by the Organisation for Economic Co-operation and Development (OECD) in collaboration with ECHA, with contribution from governments and other stakeholders. Queries could consist of a single 'query block' (i.e. only one endpoint queried) or multiple blocks built up with 'and', 'or' and 'not' functions. The eChemPortal can be accessed at https://www.echemportal.org/echemportal/. The portal allows the user to conduct searches based on substance, properties and classifications. The 'properties' search function was used to build up queries for screening and definitive data in ECHA REACH, in order to assess substances as P/vP, B/vB, T and M/vM. Screening queries were built for P/vP, B/vB and M/vM, resulting in F2 assignments. More definitive queries (i.e. using experimental test data) were built for P, vP, B/vB, T, M and vM to identify substances as 'F1'.

49. Jon Arnot BCF/BAF database

The 2006 review by Arnot & Gobas titled 'A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms' provided a database of BCF and BAF data collected from 392 pieces of scientific literature and database sources. The database comprised 5217 BCF values and 1656 BAF values measured from 842 organic chemicals in aquatic species. Data was allocated a score based on its source:

- 1: BAF (field)
- 2: BCF (total water concentrations)
- 3: BCFfd (freely dissolved concentrations)
- 4: BAF ('modelled' ecosystem)

This database was filtered to remove the low reliability data (overall score 3), as well as data for autotrophs and modelled ecosystems. Substances meeting the B/vB criteria, outlined in the methodology section of this report, were considered 'F1'.

50. Jon Arnot BMF database

The publication 'Development and evaluation of a database of dietary bioaccumulation test data for organic chemicals in fish' by Arnot & Quinn (2015) provided a database of 869 BMF values from 19 species for 477 organic chemicals. Data were scored according to High (H), Medium (M) and Low (L) confidence based on data quality and consistency with OECD guideline principles (H>M>L). Substances meeting the B/vB criteria (original measured BMF > 1) and with a reliability score of "M" or "H" were considered 'F1'.

A3.2 eChemPortal queries

The OECD's eChemPortal (https://www.echemportal.org/echemportal/) 'property search' function was used to identify future ("F1" and "F2") PBT, vPvB, PMT and vPvM substances, based on ECHA REACH data. The exact queries conducted to identify these substances are shown below.

P/vP (screening) query

Biodegradation in water: screening tests

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
% Degradation, Value fully including: < 59.9

NOT

Biodegradation in water: screening tests

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Interpretation of results
= readily biodegradable
= readily biodegradable, but failing 10-day window

NOT

Biodegradation in water: screening tests

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
% Degradation, Value fully including: > 60

P/vP (definitive) query

Biodegradation in soil

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Test guideline, Qualifier
= according to
= equivalent or similar to
Test guideline, Guideline
= OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil)
= EU Method C.23 (Aerobic and Anaerobic Transformation in Soil)
Half-life / dissipation time of parent compound, DT50 overlapping: > 60 d [h]

OR

Biodegradation in water and sediment: simulation tests

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Test guideline, Qualifier
= according to
= equivalent or similar to
Test guideline, Guideline
= EU Method C.24 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems)
= OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems)
= EPA OPPTS 835.3180 (Sediment / Water Microcosm Biodegradation Test)
Half-life of parent compound / 50% disappearance time (DT50), DT50 overlapping: > 60 d [h]

OR

Biodegradation in water and sediment: simulation tests

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Test guideline, Qualifier
= according to
= equivalent or similar to
Test guideline, Guideline
= OECD Guideline 309 (Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test)
= ISO 14592-1 (Water quality - Evaluation of the aerobic biodegradability of organic compounds at low concentrations - Part 1: Shake-flask batch test with surface water or surface water/sediment suspensions)
= ISO 14592-2 (Water quality - Evaluation of the aerobic biodegradability of organic compounds at low concentrations - Part 2: Continuous flow river model with attached biomass)
Half-life of parent compound / 50% disappearance time (DT50), DT50 overlapping: 40 - d [h]

B/vB (screening) query

Partition coefficient

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
GLP compliance
= yes
= yes (incl. certificate)
Partition coefficient type
= octanol-water
Partition coefficient, Pow type
= log Pow
Partition coefficient, Partition coefficient
overlapping: 4.5 - 10

B (definitive) query

Bioaccumulation: aquatic / sediment

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
GLP compliance
Bioaccumulation factor, Type
= BCF
= BAF
Bioaccumulation factor, Value overlapping: > 2000
dimensionless

OR

Bioaccumulation: aquatic / sediment

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Bioaccumulation factor, Type
= BMF
Bioaccumulation factor, Value overlapping: > 1
dimensionless

vB (definitive) query

Bioaccumulation: aquatic / sediment

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
GLP compliance
Bioaccumulation factor, Type
= BCF
= BAF
Bioaccumulation factor, Value overlapping: > 5000 dimensionless

OR

Bioaccumulation: aquatic / sediment

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Bioaccumulation factor, Type
= BMF
Bioaccumulation factor, Value overlapping: > 1 dimensionless

T query

Long-term toxicity to fish

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Effect concentrations, Dose descriptor
= EC10
= NOEC
= EL10
= NOELR
Effect concentrations, Effect conc. overlapping: - 0.01 mg/L

OR

Long-term toxicity to aquatic invertebrates

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Effect concentrations, Dose descriptor
= EC10
= EL10
= NOEC
= NOELR
Effect concentrations, Effect conc. overlapping: < 0.01 mg/L

OR

Toxicity to aquatic algae and cyanobacteria

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Effect concentrations, Dose descriptor
= EC10
= EL10
= NOEC
= NOELR
Effect concentrations, Effect conc. overlapping: < 0.01 mg/L

M/vM (screening) query

Partition coefficient

Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Partition coefficient, Pow type
= log Pow
Partition coefficient, Partition coefficient
overlapping: < 4.5
Partition coefficient, pH fully including: 4 - 10

M (definitive) query

Adsorption / desorption

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Adsorption coefficient, Type
= log Koc
Adsorption coefficient, Value overlapping: < 4
dimensionless

vM (definitive) query

Adsorption / desorption

Type of information
= experimental study
Reliability
= 1 (reliable without restriction)
= 2 (reliable with restrictions)
Adsorption coefficient, Type
= log Koc
Adsorption coefficient, Value overlapping: < 3
dimensionless

A4 Survey Synopsis

This Annex provides an overview of the consultations that were undertaken in this study. The full list of questions have not been presented as numerous questions fed into the analysis of each impact sub-category. There were over 100 respondents to the consultations. Figure 6-3 provides the breakdown of respondents by company size.

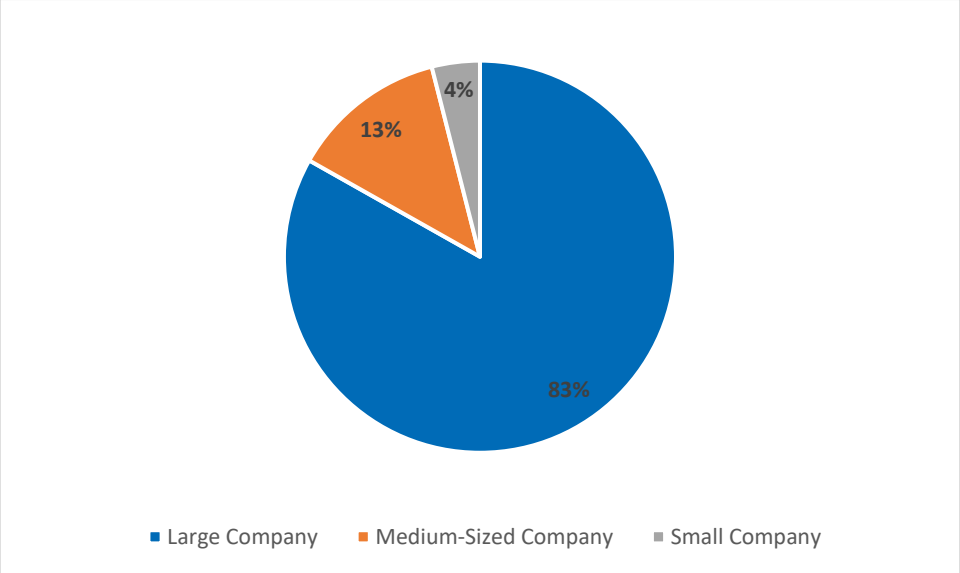


Figure 6-3 Survey Respondents by Company Size

A4.1 Consultation 1: The identification of substances of concern and product portfolio scoping

This data collection exercise sought to obtain information on the number of products, by sector, that are affected by the GRA and addition of hazards to CLP, and the potential impacts on revenue per volume. Surveyed companies were asked to complete this consultation at the beginning of the assessment.

Members were asked to identify all products within their portfolio that contain one or more substance(s) listed in the "List of Substances to be Regulated". They were asked to provide the following information on a per product basis, identified by product category:

- Volume of product manufactured in the EU-27 (2019 € and tonnes) by product
- Volume of product imported and placed in the EU-27 market without any significant adjustments (2019 € and tonnes) by product
- Volume of product manufactured in the EU-27 (2019 € and tonnes) targeting a market outside of the EU-27 (i.e. for export outside of the EU-27) by product
- Type of product: Substance, mixture, article, UVCB
- Use type/ end use: industrial, professional, consumer
- Product sector: sectors where these products sold for their end use e.g. PC8 Biocidal products[177]
- Percentage of total sales per sector
- Applicable hazard classification.

[177] Product sectors used are from the ECHA R12 guidance, Available at: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Information was requested for those products that chemical companies surveyed place on the market[178] and not products that are purchased for internal use(e.g. raw materials or intermediates) in an effort to prevent double counting.

Over 100 businesses responded to this consultation. The outputs provide us with an estimate of the size of the affected portfolio of products in the EU Chemicals sector that offers a basis for considering direct and indirect impacts on the sector's operations and contribution of the EU economy.

This consultation also offers further information that can be used to consider the potential distribution of impacts across sectors in the EU, among others.

The results from this consultation are presented in Section 4.3.

A4.2 The consideration of business and economic impacts of changes to the GRA and CLP

In order to obtain more detailed information on the potential business impacts of the addition of hazards to CLP and the extension of the GRA a second survey was launched with members. The survey was hosted on Alchemer and targeted the same sample of businesses engaged in the first consultation.

The data received in this survey formed the basis for an assessment of the extent to which the portfolio of chemicals products in the EU-27 provided in consultation 1 would indeed be affected, once businesses respond to the legislative changes e.g. through substitution, reformulation and/or applications for derogation; and quantify key knock-on effects based on evidence collected from businesses directly, as much as possible.

A four-part, 70-question survey was designed to elicit evidence and informed views from businesses:

- Part 1, gathering data about the respondents, in terms of their size, activities, main country of operation, etc.
- Part 2, seeking to form a baseline, including of their turnover, investment, expenditures, employment, regulatory burden and other key proxies of their economic activity.
- Part 3, considering direct business responses and associated costs and benefits (e.g. substitution, reformulation and/or derogations; investments; expenditures; and employment) over at least 10 years from adoption of changes to the GRA and CLP.
- Part 4, collecting information on other economic impacts, primarily qualitative (e.g. imports/exports and competitiveness).

The types of questions covered across these key business impacts and/or proxies for these impacts are outlined in Table 2-5. As outlined previously, the full list of questions have not been presented as numerous questions fed into the analysis of each impact sub-category. Below are the summary responses to selected questions.

[178] Ibid footnote 46

A5 Stakeholder views on the proposed changes

Key points

- In general, NGO's and citizens almost universally favour the replacement of the existing regulatory approach and support the CSS changes[179].
- Industry stakeholders have highlighted that legislation should not be prioritised on hazard alone, given hazards only constitute one part of the risk equation.
- Industry has raised concerns on the subjective nature of determining 'essential use' and the view that it must not lead to the adoption of intrusive judgements around what society needs[180].
- Careful evaluation of impacts on human health, environment and society (including social and economic) should be undertaken to determine a set of criteria to assess essentiality.
- Concerns that the GRA will lead to reduced ability to recycle key resources (e.g. metals and metal alloys), preventing circularity.

The proposed changes have received varied responses from key stakeholders. In general, NGO's and citizens almost universally favour the replacement of the existing regulatory approach and support the CSS changes[181]. The CSS itself highlights that ample evidence and citizens' worries justify that the GRA should become the default for the most harmful chemicals[182]. Furthermore, it has been stated that the 'essential uses' concept is compatible with current REACH provisions and can be used today[183].

As for Industry actors, there continues to be support for SRA, due to the proportionality of the GRA. The specific issues related to the CSS changes centre around the need to not prioritise based on hazards alone, the impacts of withdrawing products, the subjectivity of the 'essential uses' criteria, and potential conflict with moving towards a circular economy.

There are five recurring themes amongst the industry stakeholder feedback on the extension of the GRA. These are suitability of the extension of the GRA, regrettable substitution, SMEs, the definition of essential use and the circular economy, which are covered in detail in the following subsections and include references to the views above.

A5.1 Suitability

Industry stakeholders have highlighted that legislation should not be prioritised on hazard alone, given hazards only constitute one part of the risk equation. This contrasts with Beuc's statement on "*tier one*" substances where they stated that generic bans must "*exclusively be based on their hazard properties*".[184] The fact that some products require substances with specific physical and chemical properties means this approach may be unsuitable. The European Council of the Paint, Printing Ink and Artists' Colours Industry, Metal Packaging Europe and Food Contact Additives are some of the stakeholders expressing concerns around the substances they currently use and how they may be managed under the GRA. Their joint response argued that "*Legislation should not be prioritised on hazard alone*". The rationale of this being that some hazardous substances are essential for FCM performance, and although hazardous as a starting substance, they are safe by the final article stage[185].

[179] Jean-Philippe Montfort (2021). *Guest Column: How does the concept 'essential use of PFASs' fit the current legal framework in Europe?* [Online] Chemical Watch. Available from: https://chemicalwatch.com/198084/guest-column-how-does-the-concept-essential-use-of-pfass-fit-the-current-legal-framework-in-eu
[180] Ibid
[181] Ibid
[182] Ibid footnote 33
[183] Andrew Turley, (2021, January). *Divisions grow over who will oversee EU 'essential use' concept*. [Online] Chemical Watch. Available from: https://chemicalwatch.com/204698/divisions-grow-over-who-will-oversee-eu-essential-use-concept
[184] BEUC (2021) *Feedback on the Revision of EU rules on food contact materials.* Available from: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials/F1471824_en
[185] Metal Packaging Europe (2021) *Feedback on the Revision of EU rules on food contact materials.* Available from: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials/F1467255_en

CHEM Trust has shown support for commitments in the CSS, including those around the GRA but they are conscious of the Commission trying to use the current "*broken*" regulatory system to implement improvements, as a "*new approach*"[186]. Both DG Grow and Cefic have suggested regulatory management option analysis (RMOA) as an alternative to the GRA extension. This analysis approach would work on a case-by-case basis thus resulting in an appropriate risk management outcome.

Although some substances may be hazardous, if it is used in a product at a low concentration or if there is no exposure, the product could actually be safe in the final product stage. The Downstream Users of Chemicals Co-ordination Group (DUCC) released a paper that highlights the need to consider the clarity and predictability of risk assessment to industry and users. DUCC take the position that GRA is not able to provide adequate levels of clarity and predictability to industry and consumers[187].

Food contact materials and cosmetic products are subject to scrutiny in the extension of the GRA. Food Contact Additives (a sector group of Cefic) have highlighted that GRA for substance management would be "*over-simplified*" and "*problematic*". This is due to the fact different FCM applications require additives, for different specific physical or chemical effects. Given these different needs, a generic approach is not suitable. Furthermore the point was raised that hazards only constitute one part of the risk equation. In this way the application of the substance should be taken into account and the assessment should be on a case-by-case basis (SRA)[188].

Cosmetics Europe has confirmed the CSS aims on EDCs and generic risk management will impact the way in which the cosmetics industry is operated. But this would require the Regulation to be reassessed to meet the CSS aims[189]. Whilst the Cosmetic, Toiletry and Perfumery Association (CTPA) expressed fears that the CSS proposed changes could lead to certain cosmetics ingredients to be "unnecessarily lost" under GRA. Cosmetics and personal care products are important in everyday life and play a key role in hygiene, well-being and self-esteem. Examples were also given. For example cosmetics such as sun cream and toothpaste are clearly essential, but certain ingredients within these such as fluorinated compounds are deemed not essential. If certain substances are prohibited, finding alternatives will be required but this will likely take a long time. Furthermore, it may be that certain replacements do not have the properties required to achieve the desired effects of substances currently used[190].

A5.2 Regrettable Substitution/Absence

Leading on from this, there are fears that the extended GRA could cause the withdrawal of products such as sun cream and toothpaste that, although essential, contain ingredients that are deemed not to be. This may cause the removal of products resulting in negative impacts on physical and mental health, as mentioned by A.I.S.E. and CTPA. The risk of regrettable substitution in 'non-essential' products has also been highlighted by Euratex. For example a pre-defined decision could lead to regrettable substitutions in 'non-essential' products or uses. An example is replacing a classified substance that is controlled by safe use (that a risk assessment has already identified) with a substance with less (eco)toxicological data, or with different or greater hazards that are "*simply outside*" the scope of a restriction but that is actually more hazardous. Concerns were also raised on potential implications of changes on human health[191].

[186] Kathryn Carlson (2020) *European Commission eyes priority tier system for FCM chemicals.* [Online] Chemical Watch. Available from: https://chemicalwatch.com/195711/european-commission-eyes-priority-tier-system-for-fcm-chemicals
[187] DUCC (2020). *Comments from DUCC on CA/61/2020: Essential Uses.* Available from: http://files.chemicalwatch.com/45%20-%20DUCC%20comments_CA-61-2020_%20Essential%20uses_Redacted.pdf
[188] Food Contact Additives (FCA) (2021) *Feedback on the Revision of EU rules on food contact materials*. Available from: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12497-Revision-of-EU-rules-on-food-contact-materials/F1473248_en
[189] Kathryn Carlson, (2020). *Industry fears EU chemicals strategy will lead to 'reopening' of cosmetics Regulation.* [Online] Chemical Watch. Available from: https://chemicalwatch.com/175089/industry-fears-eu-chemicals-strategy-will-lead-to-reopening-of-cosmetics-regulation
[190] Ibid
[191] Euratex (2020) *EURATEX contribution to the policy debate on Essential Uses.* Available from: http://files.chemicalwatch.com/50%20%20EURATEX_comments_CA_61_2020_Essential%20Uses.pdf

A5.3 Small and Medium-sized Enterprises

Others have emphasised that great care should be taken to ensure that the decision-making process is transparent and non-discriminatory, and that restrictions remain proportionate. This is because there are fears that the CSS changes may disproportionally impact small and medium enterprises. SME United identified the process for deciding the definition of "essential uses" as a potential source for discrimination.

A5.4 The Definition of Essential use

In order to meet the Commission aims of only allowing the use of hazardous substances where their use is essential to society there is a need to "*define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health. These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments… Taking into account the definition of essential uses in the Montreal Protocol on Substances that Deplete the Ozone Layer, which was introduced to assess whether the use of certain chemicals is actually necessary, while acknowledging that the scope of chemicals covered by the EU chemicals regulatory framework is much broader than the specific scope of chemicals covered by the Montreal Protocol*."[192]

The concept of "essential use" is a relatively novel regulatory tool which can be traced back to a 1978 amendment to the Toxic Substances Control Act (TSCA) in the United States, which banned the use of "non-essential" aerosol sprays, and was followed by similar actions in Canada, Sweden, Norway, Denmark, and Finland.[193] The Montreal Protocol, signed in 1987, later employed the concept when phasing out the production and consumption of most Class I ozone depleting substances, while exempting those with essential uses.[194] The definition of essential use set out by the Montreal Protocol is as follows[195]:

> "*A controlled substance qualifies as essential only if:*
>
> 1. *It is necessary for the health and safety—or is critical for the functioning—of society (encompassing cultural and intellectual aspects).*
> 2. *There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.*
>
> *Production and consumption, if any, of a controlled substance for essential uses is permitted only if:*
>
> 1. *All economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance.*
> 2. *The controlled substance is not available in sufficient quantity and quality from the existing stocks of banked or recycled controlled substances*."

EU authorities are considering applying the essential use concept to justify potential derogations/restrictions under REACH, such as in the case of per- and polyfluoroalkyl substances (PFASs).[196] Furthermore, essential use will likely form part of the criteria for the GRA described in the CSS. However, as "essential use" is currently not defined by EU law, the EU has committed to defining criteria to allow the use of chemicals in this category if they indeed are shown to be necessary for health, safety and/or functioning of society, and if there are no acceptable alternatives.

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[192] Ibid footnote 33
[193] 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.
[194] EPA, (n.d). *Exemptions for Essential Uses of Chlorofluorocarbons for Metered-Dose Inhalers.* [Online] EPA. Available from: https://www.epa.gov/ods-phaseout/exemptions-essential-uses-chlorofluorocarbons-metered-dose-inhalers#:~:text=Montreal%20Protocol%20Essential%20Use%20Decision,encompassing%20cultural%20and%20intellectual%20aspects
[195] United Nations Treaty Collection, (1992) *The Montreal Protocol on Substances that Deplete the Ozone Layer, Fourth Meeting of the Parties, Decision IV/25: Essential uses.* Available from: https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties/decisions/decision-iv25-essential-uses
[196] 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

That being said, the practice of essential use will be a significant departure from the current risk assessment approach to regulating hazardous substances, and has led to some backlash from industry, as well as questions raised by other stakeholder groups. [197]

The EU environment commissioner clarified that essential uses would be based on the chemicals themselves, rather than the application(s) where the chemicals are used. In the case of the use of fluoropolymers in non-stick coatings, studies have shown exposure to be low[198,199,200], and therefore, the risk arising from the use of fluoropolymers in this application may be considered to be low. The essential use approach would nevertheless disregard conducting a cost/benefit analysis and the functioning of the EU market and would enforce a blanket ban.

In general, there here has been consensus that Article 68 is compatible with 'essential use' as a concept. Although, careful evaluation of impacts on human health, environment and society (including social and economic) should be undertaken to determine a set of criteria to assess essentiality. This would need to consider the consequences of restriction such as job creation and/or loss, as well as the potential loss of key products that serve social needs.

Cefic and other trade bodies advocate actions on case-by-case grounds. The view has been expressed that pre-defined criteria could be fraught with problems. Decision should be taken via case-by-case assessment, putting forward regulatory management option analysis (RMOA). RMOA should be used early on to identify where an essential use restriction "*could seem proportionate*".

RMOA aims to help authorities clarify whether regulatory action is necessary for a given substance. It consists of case-by-case analysis and helps identify the most appropriate measures to address a concern. The analysis is conducted by Member States or by the European Chemicals Agency (ECHA), where requested by the European Commission[201]. Cefic has also highlighted in their position paper that essential use is a relatively new concept and has a limited basis in international and European law. They note that some practical questions still remain unanswered and there is a risk that making the definition of 'essential use' too narrow could decrease circularity and lead to 'outsourcing' of the production of Green Deal solutions[202]. Regarding the essentiality criteria, DUCC mentioned that a careful evaluation of impacts on human health, environment and society (including social and economic) should be undertaken to determine a set of criteria to assess essentiality and to do so on a case-by-case basis[203].

SMEunited argued that the changes will likely conflict with other legislation and there may be potential discrimination due to the issues around the process for deciding the 'essential uses' criteria. This is because this may disproportionally impact small and medium enterprises. The 'essential use' criteria could slow down authorisation and restriction work under REACH. This may cause decision-making to be more complex and time-consuming, with "*more intense and political*" lobbying efforts on individual substances and uses. SMEunited also stated the need for a civil society-driven definition of 'essential', rather than one determined by legislators. Furthermore, the use of the concept itself may be extended beyond chemicals legislation, yet it would be difficult to do so "*without discriminating [against] one part of society".* This is due to the fact 'essentiality' can be seen as subjective, as the concept could differ depending on the age, region or culture of individuals, and may evolve with societal changes or technical development. Regarding the extension of REACH Article 68(2) to

[197] Ibid footnote 193
[198] EFSA CONTAM Panel et al.(2020) *Risk to human health related to the presence of perfluoroalkyl substances in food*. EFSA Journal. Available from: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6223
[199] Bundesinstitut für Risikobewertung, (2019). Neue gesundheitsbezogene Richtwerte für die Industriechemikalien PFOS und PFOA. DOI 10.17590/20190821-105231
[200] Heeju Choi, In-Ae Bae, Jae Chun Choi, Se-Jong Park & MeeKyung Kim (2018) *Perfluorinated compounds in food simulants after migration from fluorocarbon resin-coated frying pans, baking utensils, and non-stick baking papers on the Korean market,* Food Additives & Contaminants: Part B, 11:4, 264-272, DOI: 10.1080/19393210.2018.1499677
[201] ECHA (2021) RMOA. Available at: https://echa.europa.eu/understandng-rmoa
[202] Cefic (2020) *Defining Europe's "Essential" Chemicals For Society*. Available from: https://cefic.org/policy-matters/chemical-safety/defining-europes-essential-chemical-for-society/?utm_source=emailR&utm_medium=email&utm_campaign=Cefic%20Digital%20Dialogue%20-%20Essential%20Uses%20-%20thank%20you%20for%20attending%20-%20non%20members
[203] DUCC (2020). *Comments from DUCC on CA/61/2020: Essential Uses.* Available from: http://files.chemicalwatch.com/45%20-%20DUCC%20comments_CA-61-2020_%20Essential%20uses_Redacted.pdf

professional users, SMEunited did not express support, and raised concerns about treating highly-skilled professional users like consumers when defining REACH-restriction was also not supported.[204]

Eurometeaux have reiterated that because REACH is "*much broader*" and the related uses "*much more diverse and far-reaching*" than the Montreal Protocol, it becomes more challenging to '*pre-define*' what is essential and what is not[205]. However, ClientEarth has stated that current REACH provisions on Restrictions, including Annex XVI on socio-economic analysis are compatible with the concept of 'essential uses'. There is no incompatibility and once it has been established that a substance entails an unacceptable level of risk, the NGO argues, the annex allows ample discretion on the level of detail and scope of the socio-economic analysis. However, it must be noted this view is in contrast to the view expressed by law firm Jones Day. Jones Day argues that a legislative act is needed in order to mention essentiality among the conditions for Authorisation in Article 60(4) and possible Restriction derogations in Article 68(1), and that Annex XVI amendment is necessary as a minimum[206].

Around the 'essential use' definition, industry has raised concerns on the subjective nature of determining 'essential use' and the view that it must not lead to the adoption of intrusive judgements around what society needs[207]. The concept could differ depending on the age, region or culture of individuals, and may evolve with societal changes or technical development. This feeds into Eurometeaux, Cefic, the DUCC and SMEunited's scrutiny towards the implementation of the "essential uses" concept.

Industry has raised concerns around the subjective nature of the essential use definition as well as the view that it must not lead to the adoption of intrusive judgments around what society does and does not need. Cefic, for instance, has questioned the benefits of introducing this concept and underlined the challenge in determining which chemicals are essential to society given the uncertainty surrounding solutions for climate neutrality and circular economy.[208,209] In Cefic's view, the application of this concept would represent a radical change of the current system and remove the existing quantitative approach of assessing data such as exposure levels.[210] A.I.S.E**.** stated there is a risk that the withdrawal or absence of certain products judged non-essential could lead to more adverse effects on physical or mental health[211].

Industry organisations such as the American Chamber of Commerce to the EU (AmCham EU) have also argued that action on chemicals on the grounds of essential use could lead to unjustified regulatory measures with significant costs and greater uncertainty to businesses and consumers. AmCham EU stated to Chemical Watch reporters that ECHA's Committee for Socio-Economic Analysis (SEAC) "*weighs the socio-economic benefits of a use against the risk. SEAC assessments are comprehensive, compared to a black and white decision on whether it is essential or non-essential*"[212]. Similarly, the American Chemistry Council argued that essentiality should be determined via a comprehensive approach considering multiple factors such as safety, performance, cost, and product lifecycle. Furthermore, a chemical industry stakeholder has noted that essentiality can change with circumstances and any decisions made by government or the Commission on the definition of essential use could jeopardise economic independence, innovation and competitiveness.

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[204] SMEunited (2020) *Comment to the REACH-AP 4.3 (Essential uses).* Available from: http://files.chemicalwatch.com/Copy%20of%20Copy%20of%2017%20-%20SMEunited_comments_CA_61_2020_Essential%20uses%20%28REACH%20AP%204.3%29_Redacted.pdf
[205] Eurometaux (2021) *EUROMETAUX Response to CA/61/2020 on Essential Uses.* Available from: http://files.chemicalwatch.com/38%20-%20Eurometaux%20response%20to%20CA_61_2020%20on%20Essential%20Uses.pdf
[206] Ibid footnote 183
[207] Ibid footnote 179
[208] Cefic (2020) *Regulating Chemicals Based On The Essential Use Concept*. Available from: https://cefic.org/policy-matters/chemical-safety/defining-europes-essential-chemical-for-society/?utm_source=emailR&utm_medium=email&utm_campaign=Cefic%20Digital%20Dialogue%20-%20Essential%20Uses%20-%20thank%20you%20for%20attending%20-%20non%20members
[209] Ibid
[210] Kathryn Carlson, (2020). *Process for deciding 'essential use' criteria to come next year, says Commission official*. [Online] Chemical Watch. Available from:https://chemicalwatch.com/190355/process-for-deciding-essential-use-criteria-to-come-next-year-says-commission-official
[211] A.I.S.E (2021) *The Concept of "Essential Uses"*. Available at: http://files.chemicalwatch.com/48%20-%20AISE%20comments%20on%20essential%20uses%20CA-61-2020.pdf
[212] Leigh Stringer, (2020). *Essential use concept could lead to 'unjustified' regulatory measures, says AmCham EU*. [Online] Chemical Watch. Available from: https://chemicalwatch.com/170057/essential-use-concept-could-lead-to-unjustified-regulatory-measures-says-amcham-eu

AmCham EU also put forward recommendations in a position paper for the development of the essential use concept, stating that industry and authorities could benefit from a harmonised set of criteria to be considered when assessing essentiality for substances demonstrating unacceptable risk[213]. The proposal puts forward essentiality criteria rather than a definition for essential use, arguing that the Restriction process under REACH should follow clear guiding principles and processes, taking into consideration various factors including socioeconomic impacts, functionality, regional differences, availability of alternatives, etc. Furthermore, AmCham EU believe that applying the essential use to the PFAS Restriction process may set a precedent that can lead to unjustified and/or unenforceable Restrictions. The paper argues that essentiality should not be considered permanent, given that it requires constant effort to search for alternatives, and can therefore change according to the availability and adequacy of substitutes. It should be considered whether the use of criteria rather than a definition may lead to lengthy protracted arguments rather than establishing a clear and efficient way to derogate for those substances that are deemed to be crucial for societal functioning.

Furthermore, as stated in a webinar in September 2020, American Chemistry Council opposes applying the essential use concept to PFASs, arguing that the concept is not robust enough to justify regulatory decisions, and should not be used to undermine safety evaluations of PFASs in certain applications.[214]

In the case of GRA derogations, other industry representatives have highlighted the risks that a narrow definition of essential use may create for circularity, leading to "*outsourcing*" of the chemicals needed for society's transition to a climate neutral economy. Therefore, in certain cases, a specific risk assessment (SRA) followed by a further technical or socio-economic assessment would appear to be more appropriate. This would enable the cases where recycling benefits outweigh the risk of the substance remaining in the supply chain[215].

Moreover, some industry respondents to a European Commission document inviting CARACAL members to answer specific questions on essential use, including who should determine essentiality and how, stated that ECHA's SEAC should be responsible for making the decision through a case-by-case approach.[216,217] One industry stakeholder has pointed out that it is difficult for governments to decide what is essential in democratic societies and free markets, implying that the definition should not in fact be determined by policymakers.[218]

There are also further uncertainties surrounding the compatibility of the essential use concept with EU treaties and with World Trade Organisation (WTO) requirements.[219]

Concerns around the definition of essential use do not only come from industry. Some EU representatives have highlighted the need for a transparent definition of essential use. The EU Council of Ministers, for instance, has called for clarity on the definitions of "essential uses" in the CSS.[220] The Commission itself has noted that objectivity and relevance of the essential use definition is crucial given the potential differences in opinion over what is essential or not to society.[221] Meanwhile, in a *Chemical Watch* interview, the European Parliament's environment committee (Envi) stated that the Commission should seek to improve the definition of essential use given its misuse, particularly in the case of essential uses of chemicals in non-essential applications, to date.[222]

A key stakeholder in the preparation of the Netherlands' input to the proposed EU-wide PFAS Restriction, argued that the definition of essentiality should be decided by EU-wide policy, but derogations could be decided at the individual Member State level.[223] An EU Commission employee,

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[213] Ibid footnote 196
[214] Clelia Oziel, (2020). *Science team behind 'essential use' in EU strategy set to refine PFAS criteria.* [Online] Chemical Watch. Available from:https://chemicalwatch.com/169839/science-team-behind-essential-use-in-eu-strategy-set-to-refine-pfas-criteria
[215]Ibid footnote 33
[216] Ibid footnote 183
[217] Ibid footnote 202
[218] Ibid footnote 212
[219] Ibid footnote 202
[220]General Secretariat of the Council, (2021). *Sustainable Chemicals Strategy of the Union: Time to Deliver - Council conclusions -Annex.* Available from: https://www.consilium.europa.eu/media/48827/st06941-en21.pdf
[221] Ibid footnote 210
[222]Kathryn Carlson, (2020). Clear 'essential use' definition key for safer chemical alternatives, says Envi vice-chair. [Online] Chemical Watch. Available from: https://chemicalwatch.com/170203/clear-essential-use-definition-key-for-safer-chemical-alternatives-says-envi-vice-chair
[223]Ibid footnote 210

heading up the REACH and CLP team, also stated that the definition must be determined by the Commission at the political level, with technical input from Competent Authorities for REACH and CLP (CARACAL).[224]

In terms of the potential role of SEAC in determining essentiality, an Austrian representative argued that SEAC and its sister body, the Committee for Risk Assessment (RAC), are not competent to discuss essentiality, and instead proposed the creation of a new committee of experts in ethics, sociology and cultural anthropology for this purpose.[225]

Some NGOs support the concept of essential use under the basis that it is compatible with current REACH provisions. For example, ClientEarth has stated that the concept of essential use can be immediately be applied to EU Restriction and Authorisation decisions, particularly in the case of PFAS.[226] A Chemical Watch conference also produced the consensus that Article 68, which requires authorities to take into account socio-economic consequences of a proposed Restriction, potentially allows for the inclusion of the essential use concept.[227] Furthermore, charity CHEM Trust told Chemical Watch that properly defined essential use criteria could serve as a powerful tool in enabling regulators to consider benefits for the whole of society rather than justify exemptions for hazardous chemicals via a narrow cost-benefit approach.[228]

With regard to the question as to who will come up with the definition for (non)-essentiality, the NGO ChemSec has argued that the definition of essential use cannot be established by scientists or companies profiting from the chemicals in question, but by policymakers and by decoupling the essential use concept from the economic considerations which currently play a key role within REACH.[229] That being said, the organisation has suggested that discussions of "essential" products, sectors, and users, in addition to chemicals, could factor into the definition of essentiality.[230]

In terms of the role of SEAC, ClientEarth's response to a European Commission document inviting Caracal members to answer specific questions on essential use was that SEAC should have only a limited role in case-by-case analysis, and that the final decision, being political in nature, should belong to the Commission and Member States.[231]

A5.5 Circular Economy

There are also industry concerns that the GRA will lead to reduced ability to recycle key resources (e.g. metals and metal alloys). As a consequence, this may prevent circularity. Industry has also highlighted the risk that making the definition of 'essential use' too narrow could decrease circularity and lead to 'outsourcing' of the chemicals needed for society's transition to a climate neutral economy. Therefore, in certain cases a SRA followed by a further technical or socio-economic assessment would appear to be more appropriate. This would enable the cases where recycling benefits outweigh the risk of the substance remaining in the supply chain[232].

Finally, as for views on the extension of GRA to professional users one stakeholder expressed they did not support treating highly skilled professional users like consumers when defining REACH-restrictions.

[224]Ibid footnote 212
[225] Ibid footnote 183
[226]Clelia Oziel, (2021). *REACH change not necessary for essential use concept – NGO*. [Online] Chemical Watch. Available from: https://chemicalwatch.com/212072/reach-change-not-necessary-for-essential-use-concept-ngo
[227] Ibid footnote 179
[228]Ibid footnote 214
[229]Ibid footnote 183
[230]Ibid footnote 210
[231] 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
[232] Ibid footnote 36

A6 Methodology

This annex provides additional details of the methodology employed for the assessment of business impacts and knock-on economic effects that could potentially result from the implementation of changes to CLP and the GRA, which was covered in Section 0. In particular, three aspects are explored:

- Baseline estimation
- Knock-on effects to the wider economy
- Annualization of impacts

A6.1 Baseline estimation

This study defined and characterised how the EU Chemicals sector would likely evolve without any further policy changes in EU Chemicals legislation, drawing from Tool #14 and Tool #17 of the EC's Better Regulation Toolbox. This includes:

- Defining the **'Do nothing' policy scenario**, that is, what the EU Chemicals legislation would look like in the absence of the CSS;
- Identifying key economic and sectoral indicators that can be used to characterise the potential evolution of the **EU Chemicals sector;** and
- Quantifying how these indicators may evolve over a period of 20 years (2020-2040).

First, policy experts from the study team defined what the 'Do nothing' scenario would look like in terms of EU Chemicals legislation. In particular, the study team experts confirmed the existing legislation and the legislative changes that are already expected for implementation over the period without the need for the EC to take any further legal action.

From a business perspective, it was assumed that the existing framework would continue broadly as-is over the period, which would include periodical harmonised classification and labelling (CLH) updates to the CLP Regulation and subsequent poison centre notification (PCN) updates.

Secondly, the team established a set of indicators of focus to characterise the baseline of the EU Chemicals sector and the EU-27 economy, which would become the quantitative baseline against which the policy options would be assessed. Table 6-13 below outlines the selected indicators, based on their relevance and the evidence available from Cefic and Eurostat.

Table 6-13 Sectoral indicators selected for baseline characterisation[233]

Theme	Indicators
GDP and growth	• Sectoral output or production value or turnover (€ billions) • Sectoral Gross Value Added (€ billions), approximately capturing the sector's contribution to Gross Domestic Product) • Gross investment (€ billions) • Operating expenditure (€ billions) • Research and Development expenditure (€ billions)
Regulatory burden	• One-off or recurring regulatory costs (€ billions)
Employment	• Number of jobs supported by the sector (Number of jobs)

[233] International trade and competitiveness were not quantitatively assessed due to the study's scope and limited availability of evidence and, therefore, a detailed baseline characterisation was not carried out at this stage.

Historical evidence and data were collated from multiple, publicly available sources. Table 6-14 provides an overview of these sources for each indicator.

Table 6-14 List of economic indicators and statistics used in the definition of a baseline and analysis of impacts

Indicator	Scope	Sources
Turnover	• Geo: EU-27, Germany and France • Time: 2008-2019 • Other: chemicals sector, NACE Rev. 2 Code C20	• Eurostat Structural Business Statistics • Cefic Facts and Figures 2021 • Cefic Facts and Figures 2021 - Country reports
Gross Value added (GVA)	• Geo: EU-27, Germany and France • Time: 2008-2019 • Other: chemicals sector, NACE Rev. 2 Code C20	• Eurostat Structural Business Statistics
Intermediate consumption/ Opex	• Geo: EU-27, Germany and France • Time: 2008-2019 • Other: chemicals sector, NACE Rev. 2 Code C20	• Eurostat Structural Business Statistics
Capital expenditure	• Geo: EU-27, Germany and France • Time: 2008-2019 • Other: chemicals sector, NACE Rev. 2 Code C20	• Eurostat Structural Business Statistics
R&D	• Geo: EU-27, Germany and France • Time: 2008-2019 • Other: chemicals sector, NACE Rev. 2 Code C20	• Cefic Facts and Figures 2021 and Country Reports
Regulatory burden	• Geo: EU-27, Germany and France • Time: 2008-2019 • Other: chemicals sector, NACE Rev. 2 Code C20	• Cefic Facts and Figures 2021 and Country reports
Employment	• Geo: EU-27, Germany and France • Time: 2008-2019 • Other: chemicals sector (NACE Rev. 2 Code C20) and whole economy	• Eurostat Structural Business Statistics • Eurostat LFSI_EMP_A
GDP	• GDP historic series and baseline projections for EU countries (2020-2040) • GDP deflator historic series and baseline projections for EU countries (2020-2040) • Population historic series and baseline projections for EU countries (2020-2040)	• OECD long-term macroeconomic projections[234] • Eurostat NAMA_10 • Eurostat NAIDA_10 • European Commission – Spring 2021 Economic Forecast

[234] OECD, (2018) *GDP Long-term forecast (indicator)*, [Online] doi: 10.1787/d927bc18-en, Available from: https://data.oecd.org/gdp/gdp-long-term-forecast.htm

Some data gaps were identified, which rendered the data series incomplete for some of the economic indicators at the EU-27 chemicals sector level. These gaps were addressed by employing data available at the sub-sector and country levels for EU-27 and employing trend analysis or other reasonable assumptions to address said gaps.

Once a historical dataset was completed based on the best evidence available and expert input, regression analysis techniques were employed to estimate sectoral turnover over the next two decades (2020-2040). A pooled Ordinary Least Squares model was specified to quantify the historical relationships between sectoral turnover (the dependent variable) and real GDP growth, population growth and a time trend (the independent variables).

These estimated relationships were coupled with projections of real GDP capita and population by public institutions such as Eurostat and the OECD to produce turnover projections.

All other selected variables were estimated based on their relationship with turnover, as summarised in the Table below.

Table 6-15 Baseline projection of the other, selected indicators

Indicator	Method of projection
Output/ production value	Economic output or production value projections are computed as a proportion of turnover, based on the average historic ratio of turnover to economic output/production value from 2008-2018.
Gross Value added (GVA)	GVA projections are developed from the difference between production value and intermediate consumption.
Intermediate consumption/ Opex	Intermediate consumption is estimated based on the extrapolation of the historical trend of intermediate consumption per unit of production. The cumulative growth of intermediate consumption per unit of production over the period 2008-2018 is assumed to continue, only more spread over time, for 2019-2040. Opex is assumed to follow similar annual growth as intermediate consumption.
Capital expenditure	Capital expenditure is estimated based on the historical average capex per unit of turnover from 2008-2018.
R&D	R&D expenditure is estimated to follow a similar growth pattern as turnover, although this is likely to be conservative.
Regulatory burden	Baseline regulatory burden is expected to remain constant as a % of turnover, based on Technopolis Group, VVA. (2016) and Cefic Facts & Figures reports.
Employment	Number of employees is computed by assuming a relatively constant relationship in employment per unit of turnover, whilst taking into account employment stickiness observed in the past (i.e., slower downward adjustments, based on historical evidence and the evidence collected through a bespoke survey).

A6.2 Knock-on effects to the wider economy and Input-Output methodology

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the policy options on the EU chemicals sector have been estimated using an Input-Output methodology.

First, GVA measures the contribution that the EU-27 chemical industry makes to the economy. The two methods of measuring GVA used in this analysis are:

- The production approach that estimates the value of the goods and services produced minus the value of inputs into their production (such as raw materials)
- The income approach that determines the incomes earned by businesses and workers in producing these goods and services

Secondly, the total impact of a policy change in the sectoral GVA equals the sum of:

- Direct impact, that is, the immediate effect of a policy change on the sectoral production and, thus, its value added; and
- Indirect impacts, that is, any impacts on the sector's value chain, which would be reflected in changes to the intermediate demand for inputs to other sectors; and
- Induced impacts, that is, knock-on effects on the broader economy attributed to how the direct and indirect effects may result in changes to the compensation of employees, which would cause further changes in final demand and spending throughout the whole economy.

The direct effects have been estimated by drawing on a survey of businesses and publicly available data.

The Leontief or Input-Output model, and the associated matrices of economic activity and interconnectedness, provides a methodology for estimating the indirect and induced effects, or the knock-on effects on the economy associated with the direct impacts on the chemicals sector.

This model allows us to estimate the multipliers or factors that represent how one euro spent in one sector results in economic activity throughout the supply chain and/or other sectors and so on and so forth).

- Type I multipliers capture the direct and indirect effects only (that is, Type I multiplier – 1 would capture the indirect effects or the economic impacts throughout the supply chain).
- Type II multipliers also capture the induced effects, under the implicit assumption that final consumers do not change their final consumption patterns in response to changes in income (that is, Type II – 1 would capture the indirect and induced effects or the impact throughout the supply chain as well as the effects on the wider economy resulting from changes in compensation to employees).

For the production approach, the cumulative Type I and Type II multipliers have been assumed at around 2.8 and 3.4 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

For the income approach, the cumulative Type I and Type II multipliers have been assumed at around 2.1 and 3.1 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

A6.3 Annualization of total impacts and costs

Where required, Equivalent Annual Costs or Impacts were calculated for the selected indicators.

First, the Net Present Value (NPV) of any impact or cost over the period 2021-2040 was estimated by summing the projected cost over the period and discounted at a real discount rate of 4% in line with the Commission's Better Regulation Toolbox #61[235]. The following equation was employed.

Equation 6-1 $NPV = \sum_{t=0}^{n} \frac{C_t}{(1+r)^t}$, where n refers to the time period from 2021-2040, Ct refers to the costs or impacts in time period t, and r refers to the real discount rate.

Secondly, the NPV of the cost or impact was multiplied by an annualization factor, pertaining to the period of policy impact, which is 2023-2040. This factor is given by the following equation.

[235] European Commission (2008), *Tool #61. The Use Of Discount Rates*, Available from: https://ec.europa.eu/info/sites/info/files/file_import/better-regulation-toolbox-61_en_0.pdf

Equation 6-2 $AF = \mathrm{r}/[1-(1+r)^{-t}]$, where *r* refers to the real discount rate and *n* refers to the number of periods. Note that this formula and approach were adapted to account for the timetable of policy implementation. No impacts are expected before 2023.

T: +44 (0) 1235 753000

E: enquiry@ricardo.com

W: ee.ricardo.com