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Impact Assessment of the Chemicals Strategy for Sustainability – European Fragrance Industry

Report for the International Fragrance Association (IFRA)

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Executive summary

Introduction

This study has been commissioned by the International Fragrance Association (IFRA) to assess the business impacts to the European (EU) fragrance industry of selected actions from the EU Commission's (EC) Chemicals Strategy for Sustainability (CSS): Towards a Toxic-Free Environment[1].

The European Union has one of the most comprehensive and protective regulatory frameworks on chemicals in the world, supported by the most advanced knowledge base globally. The manufacture and use of chemical substances within the EU must comply with a comprehensive legislative framework, which is increasingly becoming a model for safety standards worldwide, to ensure a high level of protection of human health and the environment[2], whilst also maintaining the functioning of the single market. 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 by the European Commission in December 2019 and aims to transform the EU into a modern, resource-efficient and competitive economy, to improve the wellbeing and health of citizens and future generations. It will focus on tackling environmental challenges which are a threat to Europe and the world, including climate change, environmental degradation and atmospheric warming[7]. 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*"[8].

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 strategy strives for a toxic-free environment, where chemicals are manufactured and used in a way that maximises their contribution but avoids causing harm to the planet and the population, both now and for future generations. The CSS envisages industry in the EU as a globally competitive player in the production and use of safe and sustainable chemicals. The strategy lays out a pathway of actions which aim to simplify and strengthen the chemicals legislative framework, helping to build a comprehensive knowledge base to support evidence-based policy making in order to support the innovation of safe and sustainable chemicals and help to protect human health and the environment.

Study Aims and Scope

The aim of this study is to gather evidence of how specific proposals within the EU CSS and, in particular, the extension of the Generic Risk Approach (GRA); addition of hazards to the Classification, Labelling and Packaging (CLP) Regulation (EC) No. 1272/2008[9]; and the introduction of a mixture

[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] European Commission (2021) *Chemicals are everywhere*. Available from: https://ec.europa.eu/environment/chemicals/index_en.htm
[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] European Commission (2021) *A European Green Deal: striving to be the first climate-neutral continent.* Available at: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[8] Ibid footnote 7
[9] *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

assessment factor (MAF)[10], may affect fragrance businesses and the wider EU fragrance industry. The work has followed the EU Commission's Better Regulation Guidelines[11] where possible, although this is an analysis of business impacts only and so **costs and benefits to human health and the environment have not been considered**. Impacts to human health and the environment will likely be considered separately in the European Commission's impact assessments related to the CSS.

This report presents a qualitative assessment of the essential use concept and the findings of an analysis of the business impacts of:

- The addition of new hazard classes to the CLP Regulation (EC) No. 1272/2008
- The extension of the Generic Risk Approach (GRA) to additional hazard classes.

This study ran from May to December 2021. The study scope is the compliance and operating costs incurred by chemicals companies which place fragrance products on the market (manufacture, import, formulation and sale) in the EU-27. The MAF case study module is due for completion in Q1 2022 and shall be presented in a separate report.

Policy Context

Chemicals are everywhere in our daily life and play a fundamental role in most of our activities. These chemicals are the constituents of virtually every product and device we use – they contribute to our wellbeing, and in some cases even help to protect our health and security. They are also the building blocks of materials and products which contribute to low-carbon, zero pollution and energy- and resource-efficient technologies. However, chemicals with hazardous properties can cause harm to human health and the environment. As chemicals have such a wide range of 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 particularly applies to chemicals which exhibit hazardous properties such as those which can cause cancer or gene mutation, affect the reproductive, endocrine or immune systems, are persistent, bioaccumulative, mobile or toxic to the environment. Exposure to these harmful chemicals is not only a threat to human health, but also to the planet as a whole, with chemical pollution impacting and amplifying climate change, biodiversity loss and environmental degradation.

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 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)[12], and Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of hazardous substances (CLP)[13].

As the primary 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

[10] The assessment of the impacts of the introduction of a Mixture Assessment Factor carried out in this study concerns a MAF of 10 only.
[11] European Commission (2017) *Better regulation: guidelines and toolbox.* Available from: Better regulation: guidelines and toolbox | European Commission (europa.eu)
[12] *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
[13] Ibid footnote 9

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[14,15,16,17,18].

Context: Hazard Communication

In the EU, hazard communication is regulated by the CLP Regulation through harmonised criteria for classification of substances and mixtures, and rules on labelling and packaging. The CLP Regulation entered into force in 2009, and since 1 June 2015, 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[19].

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 classification and labelling system[20]. 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[21].

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

There have traditionally been two main approaches to risk management in the EU chemicals acquis; 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)[22]. These two 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).* [23]
>
> ***'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'*[24]

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 under REACH Restriction, in particular Article

[14] 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
[15] Ibid footnote 3
[16] Ibid footnote 4
[17] Ibid footnote 5
[18] 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
[19] 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
[20] United Nations Economic Commission for Europe (UNECE). (n.d.). *About the GHS*. Available from: https://unece.org/about-ghs [Accessed on 09/2021]
[21] 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
[22] European Commission, (2019). *Commission Staff Working Document Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries SWD/2019/199 final/2. Available from:* EUR-Lex - 52019SC0199 - EN - EUR-Lex (europa.eu)
[23] Ibid footnote 1
[24] Ibid footnote 1

68(2), and through sector specific legislation. It is generally applied across EU chemicals legislation in line with five main scenarios:

1. If there is a need to obtain and pass on information to enable [further/specific] risk assessment or risk management.
2. In widely dispersive or open applications which result in a significant exposure of humans or the environment.
3. In applications where the exposure is considered to be more difficult to control and monitor.
4. In applications resulting in exposure of vulnerable groups (e.g. children).
5. To prioritise the risk assessment of certain chemicals and under certain conditions.

EU chemicals legislation incorporates the specific approach in two main ways[25]:

- **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.
- **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.

Table 0-1 compares the two main risk management approaches.

Table 0-1: 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.	• Performed on a case-by-case basis and 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. • 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.

[25] Ibid footnote 4

Overview of Methodology

The European Commission's Better Regulation Guidelines and Toolbox[26] 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.

Table 0-2: Methodology used aligned with Better Regulation Guidelines.

Step	Methodology description
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 fragrance 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, any indirect economic impacts driven by these, were not in scope of this exercise, which is focussed on the fragrance 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 primarily. 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 fragrance sector.

[26] Ibid footnote 11

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 0-3 presents the limitations of the methodology and the implications these have had on the analysis.

Table 0-3: Limitations of the methodology and subsequent 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 regulatory changes that 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 fragrance sector and whether and how this would interact with the impacts of legislation. • How grouping of chemicals will affect the speed of regulation	An estimate of how grouping may expediate regulatory action has been included in the weighting of hazard classifications. This is based on limited evidence and the grouping of chemicals may result in much faster regulatory management.
Data available is in some cases limited and disproportionately representing 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 disproportionally represents large firms in terms of turnover. Likewise, the scope of products analysed is limited to those containing ingredients and raw materials produced in quantities above 1 tonne, which further limits the representativeness of smaller firms in the EU fragrance industry.	It has been 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. 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. The portfolio of products considered for analysis has been limited to those containing ingredients and raw materials in quantities above 1 tonne, due to feasibility considerations by the fragrance industry.
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 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.	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 for Assessment

Whilst the CSS does not include detailed guidance on the proposed actions around the GRA, it does indicate expected actions that will be taken by the Commission. For the purpose of this assessment, the proposed actions are carried forward as policy options.

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
- Introduction of the essential use concept.

These policy options, that is, the changes to CLP, the GRA and the concept of essential use, are described below, followed by more detail and the expected timings for implementation in Table 5-1. For the changes to CLP and the GRA assumptions were previously developed by the study team and the European Chemical Industry Council (Cefic), based on a literature review of publicly available information, and have subsequently been taken forward for use in this assessment for IFRA. The assessment of the concept of essential use is purely qualitative due to the nature of the action and the lack of current guidance or a definition provided by the European Commission.

Changes to the CLP

New hazard classes (Endocrine Disruptor (ED), Persistent, Bioaccumulative and Toxic (PBT), Very Persistent, Very Bioaccumulative (vPvB), Persistent, Mobile and Toxic (PMT), Very Persistent and very mobile (vPvM), Immunotoxicants and Neurotoxicants) will be included as part of CLP. The direct impact of these changes is primarily an increase in administrative or compliance activities, including but not restricted to, the update of labels, Safety Data Sheet (SDS), renotification to the Classification and Labelling Inventory (CLI) 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., industrial uses, as seen for CMR category 2 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 and other businesses including clients, expectations from consumers and professionals, voluntary initiatives such as 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 under REACH Restriction (including Article 68(2)) and sector specific legislation.

Table 0-4 provides the shortlist of policy options that were identified in step 2 of the methodology and the assumptions that were used in this analysis. As described above, assumptions were previously developed by the study team and Cefic, and subsequently brought forward for use in this assessment.

Two timelines are used in this assessment, a faster implementation timeline based on the CSS Action plan and a phased timeline for implementation presented in Table 0-4 below, which reflects the need for Commission impact assessments to be carried out and the adaptation of relevant legislation.

Table 0-4: Shortlist of Policy Options and Assumptions Used in the Analysis

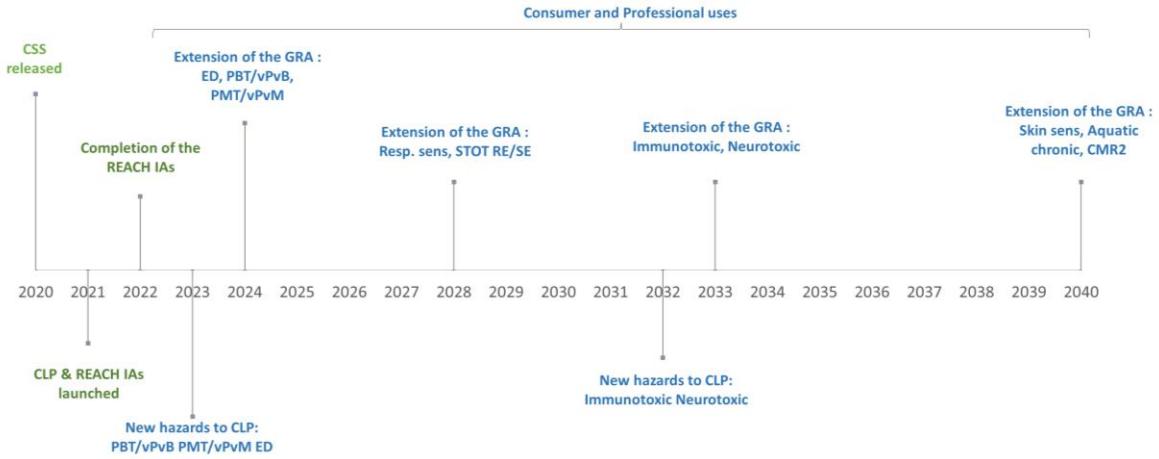
Action	Concrete Policy Option	Assumed regulatory action	Assumed entry into force

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) • persistent, mobile, toxic (PMT) • very persistent, very mobile (vPvM) Hazard classifications brought across from REACH: • persistent, bioaccumulative, toxic (PBT) • very persistent, very bioaccumulative (vPvB) Hazard classification separated from established building blocks: • Immunotoxic • neurotoxic.	2023 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 users via REACH Restriction (Article 68(2)) and relevant sector specific legislation • ED • PBT/vPvB • PMT/vPvM	2024
		Extend the generic risk approach to consumer and professional users via REACH Restriction (Article 68(2)) and relevant 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 users via REACH Restriction (Article 68(2)) and relevant sector specific legislation • Immunotoxic • Neurotoxic	2033
		Extend the generic risk approach to consumer and professional users via REACH Restriction (Article 68(2)) and relevant sector specific legislation • CMR Cat. 2 • Skin sens. Cat. 1, 1A, 1B • Aquatic chronic 1 and 2	2040

Figure 0-1 presents the indicative timeline that has been assumed in Scenario 1 of 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.

Figure 0-1: 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 assumes 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 acknowledged that the Restriction Roadmap presents the restriction of skin sensitisers most likely before the extension of the GRA and discussion with the Commission has indicated that skin sensitisers may not be included in the GRA. Should the Commission follow the hierarchy of hazard, it could be assumed that skin sensitisation would be of lower priority than respiratory sensitisers or STOT RE/SE and so for the phased implementation timeline, the restriction of skin sensitisers have been moved to 2040. 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.

The Concept of Essential Use

The CSS has put forward a proposal to introduce a derogation from the restriction of use of hazardous substances based on essential use. This is expected to feature under all extensions of the GRA and in the revision of REACH Restriction (Article 68(2)).

As mentioned, this study includes a qualitative assessment of the potential use of the concept based on literature and comparable examples such as the Montreal Protocol on Ozone Depleting Substances. The assessment builds upon previous studies on the concept, from a scientific, industrial and regulatory perspective with particular detail concerning the possible impact this concept may have on the fragrance sector.

The expected approach of this concept is for all restricted substances to be assumed non-essential unless the applicant can provide the proof of essentiality. This proof will depend on the, yet to be defined, criteria for essential use. The direct impacts of the introduction of this concept will be the loss of products which are judged to be “non-essential” as well as an increased burden for industry to provide the proof of essentiality. This study does not quantitatively assess the impacts of the essential use concept.

Assessment Conclusions

According to Eurostat[27], the EU-27 Fragrance sector comprises around 800 firms and employs more than 19,000 people in the EU-27. In 2019, these companies manufactured substances, blends and mixtures and placed them in the EU-27 market for a value of €8 billion, of which almost one third 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 fragrance 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 fragrance 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, participants had to identify all products that they placed on the market in the EU-27 or manufactured for export that contained any of the substances included in the List of Substances to be Regulated. The List of Substances to be Regulated, was created based on CSS actions to act as the basis for the screening of product portfolios. The list was developed through the use of publicly available information on hazardous substances and contained over 12,000 substances which either currently or may in the future be classified as:

- Carcinogen (C) category 1A, 1B, 2;
- Mutagen (M) category 1A, 1B, 2;
- Toxic for reproduction (R) category 1A, 1B, 2;
- Persistent, bioaccumulative, toxic (PBT);
- Very persistent, very bioaccumulative (vPvB);
- Persistent, mobile, toxic (PMT);
- Endocrine disruptor (ED) for human health and/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, 1B;
- 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.

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"

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 a substance which was present on the "List of Substances to be Regulated", rather than the extent to which they might be affected, which is considered through the second consultation outlined in section 2.5.

[27] 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. All employment figures are expressed in FTE units.

Data on 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 30 businesses:

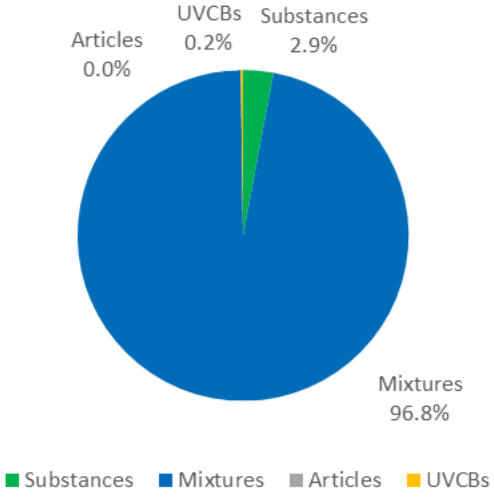
- Volume of products manufactured in the EU-27 (€ and tonnes) by product
- Volume of products imported and placed in the EU-27 market without any significant adjustments (€ and tonnes) by product
- Volume of products manufactured in the EU-27 (€ and tonnes) targeting a market outside of the EU-27 (i.e., for export outside of the EU-27) by product
- Type of product: Substance, mixture, article, or substances of unknown or variable composition, complex reaction products, or biological materials (UVCB)
- Use type/ end use: industrial, professional, consumer
- Product sector: sectors where these products are sold for their end use e.g., PC28 perfumes, fragrances[28]
- Percentage of total sales per sector
- Applicable hazard classification

30 businesses, 8 large, 6 medium-sized and 16 small, 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). The outputs provide us with an estimate of the size of the affected portfolio of products in the EU Fragrance sector that offers a basis for considering direct and indirect impacts on the sector's operations and contribution of the EU economy. In this case, the size of the potentially affected product portfolio was estimated to be around 27% of the sector's turnover, which would be equivalent to more than €2.2 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 (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). As expected, most of the production portfolio reported as containing new and/or future potential hazard classifications in the fragrance industry are mixtures instead of single substances. This composition is shown in Figure below.

[28] ECHA, 2015, *Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use Descriptions*, Version 3.0. Available from: R_12_CARACAL_cross_check_TC (europa.eu)
This study also included products in the following categories which include fragrances, PCU, PC0, PC39, PC28, PC19, PC29, PC3, PC35, PC26, PC14, PC1, PC8, PC27, PC20, PC15, PC21, PC31, PC51

Figure 0-2 Breakdown of the products with new and/or future potential hazard classifications as reported by surveyed companies in the fragrances sector.



Available evidence, past experience of the implementation of EU chemicals legislation 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).

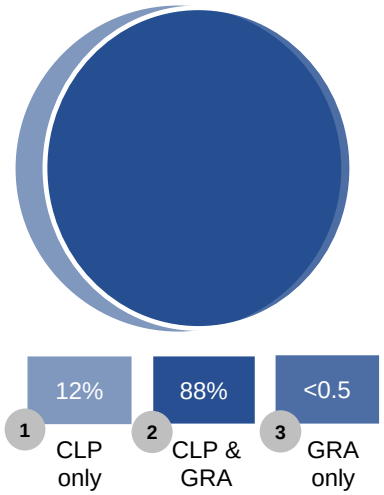
After these adjustments are applied, the size of products in scope of being affected by the policy changes by 2040 would be lower and around 25% of the estimated sectoral turnover, which would be equivalent to more than €2.0 billion of the 2019 market.

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

Expected business response

The evidence collected for the study commissioned by IFRA suggests that, in response to the affected portfolio that may face direct restrictions/bans introduced by the extension of the GRA (88% of the total affected portfolio), businesses will substitute and/or reformulate around 33% of these products to mitigate the market losses.

Figure 0-3 Breakdown of the potentially affected portfolio of products by policy change (where 100% is equivalent to the size of the total potentially affected portfolio of products)



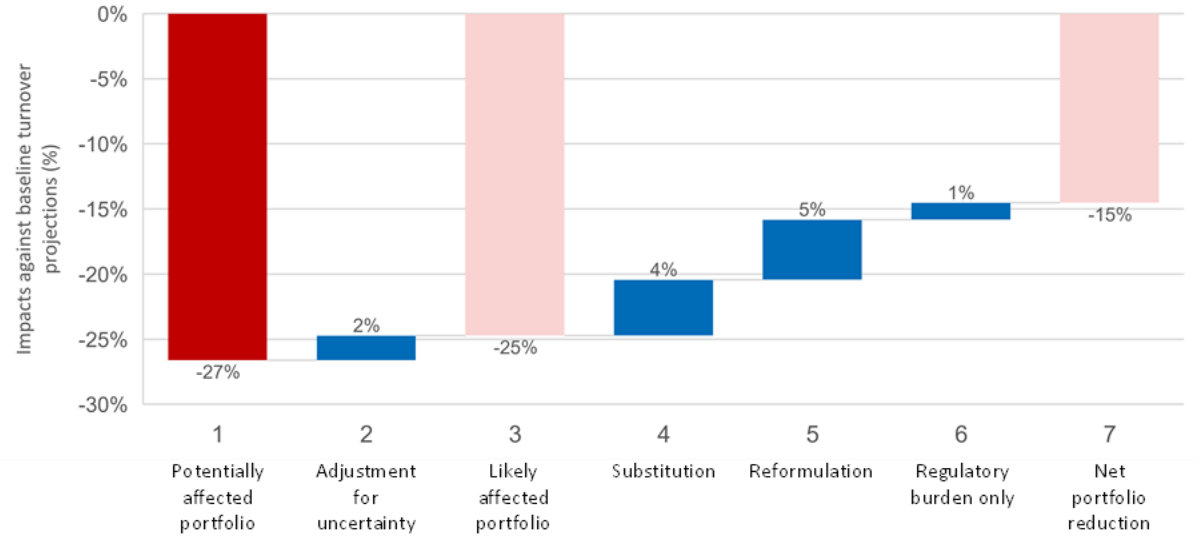
Source: Ricardo analysis based on Eurostat data and a bespoke survey to fragrance companies.

In addition, a quarter of the products that may only be affected by changes to CLP are expected to face pressures for market withdrawal (equivalent to 3% of the total affected portfolio). These businesses will also be able to substitute and/or reformulate some of their products to mitigate potential market losses.

The other three quarters of the products that may only be affected by changes to the CLP (equivalent to the remaining 9% of the total affected portfolio or 1% of total market value) will only be subject to increased regulatory burden. In this case, the evidence collected suggests that businesses have some capacity to pass through some of this regulatory burden to their clients. Additionally, the survey responses suggest that overall sales of the EU fragrance sector are not very responsive to price changes (i.e., sales decrease proportionally less than a given increase in prices). 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.

Figure below summarises how these adjustments interact with the likely portfolio in scope, having adjusted for uncertainty in classifications (F1/F2).

Figure 0-4 Stepwise representation of the portfolio in scope of being affected by the policy changes as well as the estimated strategies that businesses may take to mitigate any impacts on business discontinuation (i.e., substitution, reformulation, and derogation)



In brief, the total potentially affected product portfolio from potential changes to the GRA and CLP (**1**) can be adjusted by the weighting for F1/F2 classifications (**2**) to lead to the most likely affected portfolio, which is equivalent to 25% of the baseline turnover or market (**3**).

Around 9 percentage points of this market will likely be substituted (**4**) or reformulated (**5**), and around 1 percentage point of the market will be affected by increased regulatory burden due to changes to CLP but will not face pressures for market withdrawal (**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 15% or equivalent to €1.2 billion in 2019 (**7**).

The required business responses in the form of substitution and reformulation are, however, costly and will require an increase in investment and innovation, and operating expenditure. Additionally, the substitute products in this scenario are not guaranteed to present the same characteristics and performance as the ones they are intended to substitute, so it is uncertain whether they are viable alternatives and would be accepted by consumers. Demand may have an impact on the price of alternative products. It should also be noted that the ability to substitute fragrance constituents does not necessarily allow for the product to be kept on the market. As many fragrance products are complex mixtures, substitution and reformulation are also complex, and certain products cannot be reformulated and so would be deemed an alternative product

Costs and benefits driven by the impact on the EU fragrances sector

To assess the net impacts of these policy options on the EU fragrance 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 and long-term macroeconomic projections for the European economies from the OECD. This baseline scenario assumes that the CSS is not implemented, GRA is not extended, and CLP remains unchanged, except for periodical updates of Annex VI harmonised classifications.
- A first policy scenario (**Scenario 1**) considers the addition of hazard classes to CLP and extension of the GRA over a phased implementation timeline. 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 or reformulated. In addition, a quarter of products that are only affected by CLP (that is, not covered by the GRA extension) may also

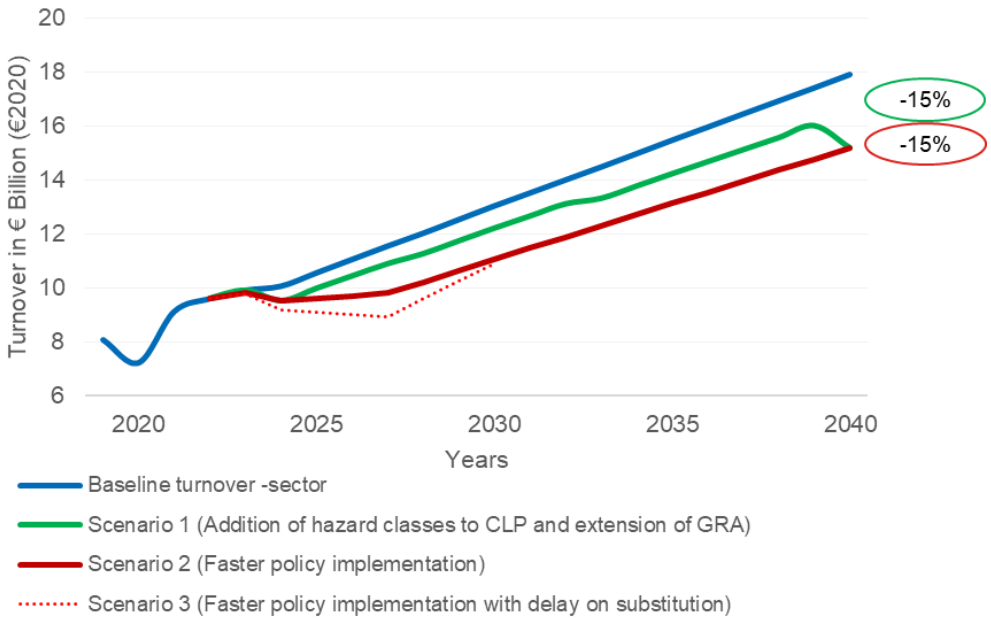
face pressures to withdraw from the market or substitute/reformulate. In a context where both CLP and GRA changes are implemented simultaneously, this impact is expected to be relatively small. Overall, in this scenario, the EU Fragrance sector is estimated to lose €0.9 billion (€2020) of turnover each year over the period 2023-2040, against the baseline scenario.

- A second scenario (**Scenario 2**) assumes a faster, 5-year implementation timetable of the expected changes to the GRA and CLP. This reflects the timeline indicated by the CSS Action Plan. The faster implementation would require earlier and faster withdrawal of substances/ products from the market or their substitution and reformulation. It is assumed that businesses are able to respond and adjust operations immediately after policy adoption, with limited or unnoticeable delays. Over time, however, the size of the EU fragrance market is expected to converge to the Scenario 1 levels. Overall, in this scenario, the EU Fragrance sector is estimated to lose €1.7 billion (€2020) of turnover each year over the period 2023-2040, against the baseline scenario.
- 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[29], it has been assumed that companies may need, on average, around 4.8 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 expected in Scenario 2. Overall, in this scenario, the EU Fragrance sector is estimated to lose €1.9 billion (€2020) of turnover each year over the period 2023-2040, against the baseline scenario.

The net impacts on the EU fragrance sector were considered over a period of 20 years, employing economic modelling on the evidence available.

This analysis reveals that **EU fragrance companies would lose between €0.9 billion to €2.0 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 business 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 €2.7 billion lower than in the baseline.

Figure 0-5 Estimated impacts on the turnover of the EU fragrances sector against the baseline scenario (€ 2020)



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

[29] 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

The direct contribution of the sector to Gross Value Added (GVA) would be between €0.3 and €0.5 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 fragrance sector to GVA would be between €0.8 and €1.7 billion lower per year over this period, on average. This would affect Member States differently, depending on the contribution of their fragrance sector to their overall economy.**

It is also estimated that operating expenditures would decline when compared to the baseline. These net reductions would be driven by the significant losses that are estimated to the size or operations of the EU fragrance market. At the same time, capital expenditure or investment would increase to sustain the needed levels of substitution and reformulation for the mitigation of further turnover losses. Based on the survey of fragrance companies, it is expected that an additional €456 million (€2020) would be invested over 10-15 years from the adoption of the policy changes to support these actions that fragrance companies would need to embark on to mitigate further operational and turnover losses. 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 around 50% on average over the period 2023-2040. Similarly, the 'ratio of OPEX to turnover' is estimated to increase against the baseline by between 3% on average over the same period. The new CAPEX and OPEX that are estimated to be spent on product innovation and administrative burden are conceptualised as the regulatory burden.

The changes to GRA and CLP would also affect the sector's employment. It is estimated that, by 2040, around 3,000 jobs in the EU fragrance sector would be lost against the baseline scenario, which is equivalent to 11% of the baseline fragrance sector workforce. **These impacts would have knock-on effects in the EU economy, which could lead to losing between 9,000 and 13,000 jobs by 2040 when compared against the baseline.**

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

Table 0-5 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 €0.9 billion per year on average against the baseline	A loss of €1.8 billion per year on average against the baseline	A loss of €2.0 billion per year on average against the baseline
Total GVA contribution (*direct, indirect, induced*)*	A loss of €0.8 billion per year on average against the baseline	A loss of €1.4 billion per year on average against the baseline	A loss of €1.7 billion per year on average against the baseline
Regulatory burden	An additional annualised burden of €258 million each year over the period	An additional annualised burden of €458 million each year over the period	An additional annualised burden of €373 million each year with a delay
Total employment contribution (*direct, indirect, induced*)*	3,700 fewer jobs, on average, when compared to the baseline in any given year	7,000 fewer jobs, on average, when compared to the baseline in any given year	11,100 fewer jobs, on average, when compared to the baseline in any given year

***Note:** The decrease in turnover in the EU fragrance 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 and its employment (induced or Type II effects).

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. From literature, stakeholder views and the analysis of comparable legislation, the impact of the essential use derogation has been qualitatively

assessed and the following conclusions made. The concept is expected to rest heavily on four main aspects: the implementation, the breadth of applicability, the evolution of the concept and the coherence with other legislation and initiatives. For the EU Fragrance Industry the final definition/criteria decided by the European Commission will be divisive in the applicability of essentiality to fragrance products. Fragrances have been linked to changes in mood and overall wellbeing. Some fragrances are also considered to be culturally important. The targeted consultation for this study asked whether stakeholders would expect the extension of the GRA or the new hazards to CLP to have an impact on the preservation of the cultural heritage of the EU-27 in the 10 years after adoption, and 77% of survey respondents to our economic consultation responded they indeed would. The consideration of wellbeing, health and cultural importance in the European Commission's essential use definition will be key to deciding the number of fragrance products considered to be essential and for which a derogation from the GRA may be sought under the essential use concept.

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 fragrances currently on the market.

The **impact on downstream users from the fragrance sector** warrants **further exploration**. Among these, the detergents and the cosmetics industries are key.

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".

To mitigate this, support would need to be provided to all the affected subsectors in 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 fragrance 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 fragrance 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.

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Glossary

Abbreviation	Definition
ATP	Adaptations to Technical Progress
BRP	Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products
CEFIC	European Chemical Industry Council
CLP	Classification, Labelling and Packaging
CLH	Harmonised Classification and Labelling
CLI	Classification and Labelling Inventory
CMR	Carcinogens, mutagens and reprotoxicants
CSR	Chemical Safety Report
CSS	Chemical Sustainability Strategy
DU	Downstream Users
DUCC	Downstream Users of Chemicals Co-ordination Group
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
EDC	Endocrine disrupting chemical
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 Risk Approach
vPvBs	Very persistent, very bioaccumulative
PBT	Persistent, Bioaccumulative and Toxic
vPBT	Very Persistent, Bioaccumulative and Toxic
PCN	Poison Centre Notifications
PFAS	Perfluoroalkyl chemicals
PMT	Persistent, Mobile and Toxic
vPvM	Very Persistent and very mobile
R&D	Research and Development
RE	Repeated exposure
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
RMOA	Risk 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	Substances 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
VCI	Verband der Chemischen Industrie

1 Introduction

1.1 Background to the Study

This study has been commissioned by the International Fragrance Association (IFRA) to undertake an independent economic analysis of the potential impacts of the European Commission's (EC) Chemicals Strategy for Sustainability (CSS): Towards a Toxic-Free Environment[30].

In December 2019, the Commission launched the European Green Deal which 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 protect our health and are the building blocks of the products that we rely on every day, playing a fundamental role in the functioning of our daily lives. There is a need to reduce harmful exposures, whilst also maintaining sustainable use due to the fact that chemicals have such wide dispersive uses and play such a key role in the functioning of society. For 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 there is a particular need to do so. Exposure to these chemicals is a threat not only to human health, but the planet as a whole, potentially contributing to global crises such as climate change, biodiversity loss and environmental degradation.

The European Union (EU) has one of the most comprehensive chemical regulatory frameworks in the world. This helps to inform regulatory actions in other regions and has become a model for the safe use of chemicals[31]. The EU has been successful in maintaining the functioning of the single market, whilst reducing the risks to human health and the environment. However, studies[32,33,34] note the need to continue to improve current practices to ensure a higher level of protection. In response to this need, the EU launched the Chemicals Strategy for Sustainability (CSS) in October 2020, to provide a new long-term strategy for chemicals policy, in line with the aims of the EU Green Deal. The main aim of the CSS it to strive 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. Approximately 80 action points are included within the strategy, seeking 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

The main aim of this study is to undertake an independent economic analysis of the potential impacts of the EC's Chemicals Strategy for Sustainability (CSS): Towards a Toxic-Free Environment. The study aimed to assess the economic impacts as a result of selected actions of the CSS on the EU fragrance industry. Analysis has followed the EU Commission's Better Regulation Guidelines[35] where possible, although as this is an analysis of economic 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 shall be considered in the European Commission impact assessments related to the CSS. The methodology and assumptions used in this study were developed by the study team for the European Chemical Industry Council (Cefic) study "Economic Analysis of the Impacts of the Chemicals

[30] 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
[31] A. Bradford (2020) *The Brussels Effect: How the European Union Rules the World*. New York: Oxford University Press
[32] 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)
[33] Amec Foster Wheeler et al, (2017). *Study supporting the Fitness Check on the most relevant chemicals legislation ("Fitness Check +")*
[34] 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
[35] European Commission (2017) *Better regulation: guidelines and toolbox.* Available from: Better regulation: guidelines and toolbox | European Commission (europa.eu)

Strategy for Sustainability" (2021) and have been adapted where needed to account for the nuances of the fragrance sector.

This report presents the findings of the study which includes a review of the actions set out in the CSS and a deeper assessment of three of the four modules selected by IFRA. These include:

- The addition of hazards to the CLP Regulation (EC) No. 1272/2008[36]
- The extension of the Generic Risk Approach (GRA).
- A qualitative assessment of essential use.

The introduction of a Mixture Assessment Factor (MAF) for chemical safety assessments shall be presented in a separate report due Q1 2022.

The study ran from May to December 2021. The study concerns the compliance and operating costs incurred by fragrance companies which place products on the market (manufacture, import, formulation and sale) in the EU-27. As this is an analysis of the economic impacts, there is no analysis of impacts to human health or the environment as a result of the proposed legislative changes.

1.3 Report Structure

This report is structured in the following sections:

- Section 1: Introduction
- Section 2: Methodology – ex ante Assessment of Economic Impacts
- Section 3: Context and Baseline Scenario
- Section 4: Policy Options
- Section 5: Business Impacts of the Policy Options
- Section 6: Essential Use
- Section 7: Conclusions

Full detail of the methodology is presented in the Annexes to this report.

[36] *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

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 economic impacts to the EU fragrance industry as a result of the selected policy options from the CSS (section 2.1). As mentioned earlier, the approach taken mirrors a methodology used by the study team in undertaking a similar assessment for The European Chemical Industry Council (Cefic). The same methodology is thus presented here.

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). Further detail on the methodology is presented in Annex 5.

2.1 Overview

The European Commission's Better Regulation Guidelines and Toolbox[37] 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 fragrance 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, as presented in Table 2-1.

Table 2-1: Methodology used aligned with Better Regulation Guidelines

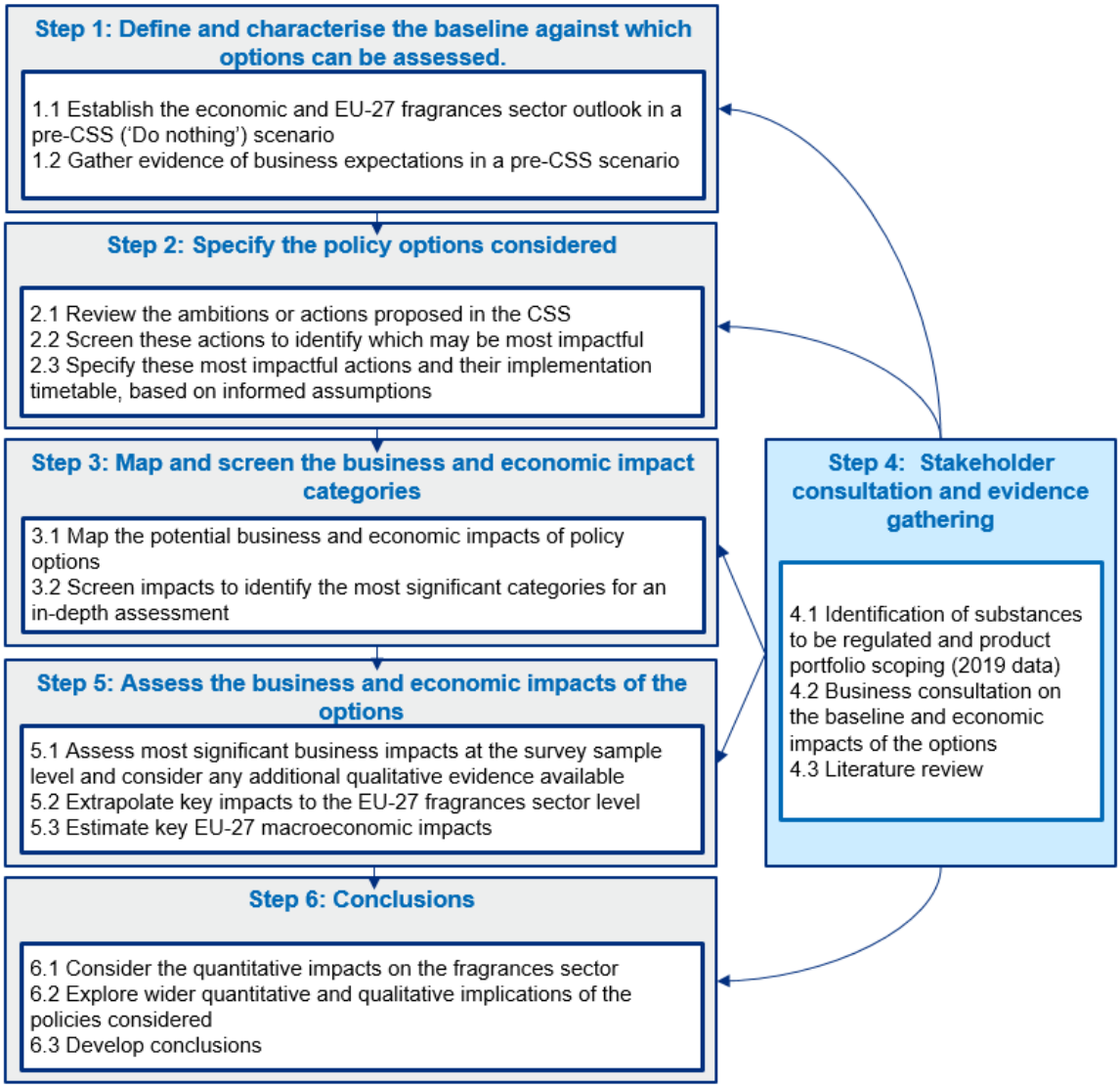
Step	Methodology description
Step 1: Define and characterise the baseline scenario against which to assess options.	The study considered how the status quo would likely evolve, including key economic and sectoral indicators at the EU-27 economy and fragrance sector level, without any further policy changes 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.

[37] Ibid footnote 35

Step	Methodology description
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, any indirect economic impacts driven by these, were not in scope of this exercise, which is focussed on the fragrances 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 fragrance 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



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 fragrance 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 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 fragrance sector;** and
- Quantifying how these indicators may evolve over a period of 20 years (2020-2040).

First, policy experts defined what the 'Do nothing' scenario would look like in terms of EU Chemicals legislation of relevance to the fragrance sector. In particular, 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.

Secondly, the team established a set of proxy indicators of focus to characterise the baseline of the EU fragrance 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 IFRA and Eurostat, Table 2-22 below outlines the selected indicators.

Table 2-2 Sectoral indicators selected for the baseline characterisation

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) • International trade and competitiveness (€ billions or qualitative)
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 IFRA 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.

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 fragrance 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.
- Established final policy options for consideration in this study.

An illustration of the shortlist is presented in Table 2-3 and more detailed outputs of this process are also described in Section 4.

Table 2-3 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, cosmetics, toys and detergents - 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) 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. d) Extend to professional users under REACH the level of protection granted to consumers e) 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 f) 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

2.4 Map and screen the economic impacts

To identify and assess the most significant impacts, a stepwise approach was taken:

- **Step 1:** Identification of long list of all potential impacts of the policy options.
- **Step 2:** Screening to select the most significant impacts for further analysis.

Step 1 involved identifying all potential impacts of the policy options. This involved constructing the chain of impacts by considering direct and indirect behavioural changes and impacts on relevant public policy goals. When mapping out all potentially relevant impacts, the following stakeholders were considered:

- Enterprises (within the C20.14 NACE sector – i.e., Manufacture of synthetic aromatic products and C20.53 NACE sector – i.e., Manufacture of essential oils)
- Workers
- Consumers
- EU citizens
- Public authorities
- Third countries.

Only economic impacts were included in the scope of this assessment, while human health, social, and environmental impacts were excluded.

Once all the potential impacts had been identified, **Step 2** involved selecting the most significant impacts for further analysis, based on the following criteria:

- The magnitude of the expected impact and whether the impact is more or less significant for certain stakeholders (i.e. SMEs, specific sub-sectors)
- The likelihood or uncertainty of an impact materialising
- The relation to the underlying initiative (i.e. whether it is a direct and/or indirect impact of the actions considered for REACH and CLP under the CSS)
- The relevance of the impact according to the commitments (i.e. whether the impact is aligned or not with the underlying objectives for amending the Regulation)
- The importance of impacts for EU objectives and policies

The screening impacts for significance was based on evidence collected through secondary research consisting of a literature review of published reports and papers, input from IFRA members and affiliated partners upstream gathered through consultation activities, and the knowledge and expert opinion of the study team.

The level of significance was assessed in terms of changes relative to the baseline.

2.4.1 Addition of Hazards to CLP Regulation

The biggest costs to the fragrance sector from Classification, Labelling and Packaging (CLP) are related to administrative requirements (i.e. update of labels, SDS, renotification to the C&L inventory and to Poison Centres and update of registration dossiers), which represents a large proportion of the overall regulatory cost. The administrative burden can be caused by the need for reclassification of substances under the CLP Regulation and the subsequent updates to hazard communication.

2.4.1.1 Direct Compliance Costs

Harmonised classification and labelling (CLH) Costs: CLH costs cover the fees associated with submitting CLH dossiers to the European Chemicals Agency (ECHA). No regulatory fees are incurred from self-classifications. It is not certain which substances will be subject to harmonised classification as a result of the introduction of additional hazard classes as the classification criteria are still to be determined.

2.4.1.2 Substantive Compliance Costs

Table 2-4 shows the possible substantive compliance costs which may to apply to IFRA members (and affiliated partners upstream), and which costs are included in each compliance category.

Table 2-4: Possible compliance costs which may apply to IFRA

Compliance Cost Category	Costs Included
Classification costs	The costs of classifying substances and mixtures are likely to include: • Gathering the available information (not including the costs of any testing as this is carried out under REACH) needed to undertake classification; • Reviewing the available information to ensure it is adequate and reliable; • Evaluating the available information against the classification criteria; • Deciding on the appropriate classification for self-classification purposes; and • Paying any consultancy fees.
Labelling costs	All products containing substances and mixtures requiring classification under the new CLP hazard classes will need to be labelled (if not already), or have their existing labels updated, due to changes in the pictograms, safety and hazard phrases triggered by a change in classification.
Packaging costs	Packaging costs include: • Re-design and testing costs; • Change in packaging material; • Change in production lines; • Disposal of obsolete packaging; and • Change in packaging design for safety. Labels may also be printed directly onto packaging, so new packaging would be triggered by changes in the pictograms, safety and hazard phrases, as well the possibility of needing to change the layout of labelling on packaging in order to fit the information onto the packaging.
SDS costs	Cost of producing, updating and distributing safety data sheet (SDS).
CSR (Chemical Safety Report) Costs	Under Article 22 of REACH, it is mandatory to update a registration with new relevant information and submit it to ECHA. A change in the classification or labelling of a substance constitutes the need for updating a resubmission of a REACH registration dossier. A change in classification would require all exposure scenarios in the CSR to be updated for every use. In addition, updating a registration dossier requires a regulatory fee.
IT/Software Costs	Companies may incur costs from updating or purchasing new IT systems for assisting with classification, labelling and SDS production activities.
Data Generation/Collection Costs	The CLP Regulation requires a manufacturer, importer or downstream user to gather relevant and available information on all hazardous properties of a substance or mixture. This can include the cost associated with performing a literature search / evidence review or fees for accessing databases.

2.4.1.3 Administrative burden

Classification and Labelling Inventory (CLI) Notification Costs:

The notification requirement extends to all substances registered under REACH, as well as all substances classed as hazardous under CLP that are placed on the market, either on their own or in mixtures above the generic concentration limit (GCL), or specific concentration limit (SCL) (if applicable). This is mainly a cost in the form of time spent.

Cost of Checking the CLI: The CLI needs to be checked as there is an obligation for suppliers to update self-classifications based on new information and to try and come to an agreement on self-classifications with all other notifiers of a substance. This is mainly a time cost.

Poison Centre Notification (PCN) Costs: Annex VIII of the CLP Regulation requires companies placing hazardous mixtures on the EU market to submit PCNs. This is mainly a time cost.

Position of Small and Medium-sized Enterprises (SMEs): Additional costs and burden on the operation and competitiveness of SMEs.

Some of these activities may be contracted out to consultants, which would incur an additional cost.

2.4.1.4 Indirect Compliance Costs

Impacts on Downstream Users (DUs) (i.e. products no longer available or at higher cost): The removal of products from the market is likely to have significant impacts on downstream users, as they may rely heavily on certain products, and they would have to adapt their activities and processes to accommodate the substitute products. Substitutes may also not be as effective and may not meet qualification or other standards. Any delay between removal of a product from the market and a replacement with a substitute may cause supply chain disruption and downstream users to halt some of their activities. This is of particular concern for downstream users of fragrance products as it can be difficult, and in some cases impossible, to substitute or reformulate a product with an alternative with the same olfactory properties.

2.4.1.5 Trade and Investment Flows

Relabelling of Imported and Exported Products: One of the biggest barriers to international trade of chemicals is the large differences in labelling requirements. The proposed changes to CLP would mean that products placed on the market outside of the EU require re-labelling according to the specific requirements of those markets. Similarly, products imported into the EU have to be re-labelled to comply with the CLP Regulation. This could impact global supply chains and create an unlevel playing field for European business versus the rest of the world.

Reduced Exports Due to Higher Costs of EU Products: The extra compliance activities may lead to increased costs for products manufactured in the EU, which in turn could result in an increase in price which would reduce competitiveness, potentially resulting in a reduction in exports of EU products.

2.4.1.6 Innovation and Research

Harmonised classification could lead to increased regulatory management of substances or mixtures that may be classified under the new hazard classes, resulting in the product being restricted and banned in other legislation. This can lead to increased investment in Research and Development (R&D) to try and find substitutes, or it could lead to uncertainty and reduce investment in R&D and innovation for many years. The additional compliance activities may also divert resources away from innovation activities.

2.4.1.7 Consumers and Households

Price, Quality, Availability or Choice of Consumer Goods: Additional compliance costs may be passed onto consumers, leading to increased prices. As mentioned earlier, as fragrances are complex mixtures, substitution and reformulation is not always possible where there is a need to products the same olfactory properties or meet industry standards, this could mean that there may be a reduction in consumer choice due to a decreased availability of certain products.

Consumer Information, Knowledge, Trust or Protection: The proposed changes to CLP could lead to consumers being more informed about the hazardous substances in their products. Greater consumer protection would be a knock-on effect of the new hazard classifications due to increased regulatory management.

2.4.2 Extension of the Generic Risk Approach (GRA)

The key impacts screened during **Step 1** are outlined in Table 2-55. Positive/negative, direct/indirect, intended/unintended and short/long-term effects were all considered during screening.

Table 2-5: Key impacts of extension to the GRA

Changes	Products Affected
Economic/ business impacts	• Operating costs and conduct of business (e.g. direct and substantive compliance costs) • Administrative burdens on businesses (e.g. costs associated with notification obligations) • Indirect compliance costs (e.g. costs for downstream users) • Position of SMEs (e.g. burden on small firms and impacts on their financial sustainability, etc.) • Trade and investment flows (e.g. imports) • Market efficiency and competitiveness of business • Functioning of the internal market and competition • Innovation and research (e.g. potential incentives to increase investment in chemical alternatives, etc.) • Public authorities: services, administrative, compliance and enforcement burden (e.g. administrative costs from additional requirements, etc.) • Consumers and households • Third countries and international • Macroeconomic environment

Following the screening of impacts using the Step 2 criteria, those impacts that are considered to be most significant in relation to the extension to the GRA were identified. These are outlined in Table 2-6.

Table 2-6: Identification of most significant impacts – extension of the GRA

Changes	Products Affected
Economic/ business impacts	• Substantive compliance costs (e.g. reformulation and substitution costs, costs of removing products from market) • Indirect compliance costs (e.g. costs for downstream users) • Trade and investment flows (e.g. imports and exports) • Competitiveness (sectoral) of business • Position of SMEs • Innovation and research • Consumers and households

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 considered across the entire fragrance value chain, including but not exclusive to manufacturers and formulators of fragrance blends and manufacturers and retailers of detergents and cleaning products; and cosmetics and personal care products. There is variation in how the EU chemicals legislation is implemented across these sectors. The available evidence which can be found in published reports and studies are 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 literature review. Due to the nature of this project, the consultation activities were not open to the wider public and targeted at IFRA members (and affiliated partners upstream) only. This was deemed appropriate for the purposes of this study as it focusses on assessing impacts on the EU fragrance sector. A total of 30 IFRA members and affiliated upstream partners were consulted and provided their views, which represent 57% of the EU fragrance 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 fragrance sector comprises around 800 companies. Across these two consultation 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 30 companies that represent 57% of the EU-27 fragrance sector output. This sample would represent the sector's mean with a 95% confidence interval and a margin of error of around +/- 10% for large companies only, while the sectorial output of SMEs is not captured in a precise manner. The overall sector's mean is thus broadly represented, although it fails to provide a 95% confidence level. More details are provided in Section 2.7.1 and Annex 4.

The sample does, however, disproportionally represent large firms in terms of turnover. 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[38].

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

i. Identification of substances of concern 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. Under the Cefic study, a list of current and potential future substances to be regulated, hereafter "List of Substances to be Regulated", was created to act as the basis for the screening of product portfolios. This list was carried forward for the purposes of this exercise.

The list was developed through the use of publicly available information on hazardous substances and contained over 12,000 substances which either currently or may in the future be classified as:

- Carcinogen (C) category 1A, 1B, 2;
- Mutagen (M) category 1A, 1B, 2;
- Toxic for reproduction (R) category 1A, 1B, 2;
- Persistent, bioaccumulative, toxic (PBT);
- Very persistent, very bioaccumulative (vPvB);
- Persistent, mobile, toxic (PMT);
- Endocrine disruptor (ED) for human health and/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, 1B;
- 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.

[38] The sample of SME respondents has a size of 22, which implies that any estimates for this group should be taken as indicative only.

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*"[39]

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 a substance which was present on the "List of Substances to be Regulated", rather than the extent to which they might be affected, which is considered through the second consultation outlined in section ii.

Data on 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 over 30 businesses:

- Volume of products manufactured in the EU-27 (€ and tonnes) by product
- Volume of products imported and placed in the EU-27 market without any significant adjustments (€ and tonnes) by product
- Volume of products manufactured in the EU-27 (€ 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 are sold for their end use e.g., PC28 perfumes, fragrances[40]
- Percentage of total sales per sector
- Applicable hazard classification

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

ii. 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 fragrances in the EU-27 would indeed be affected,** once businesses respond to the legislative changes e.g., through substitution and reformulation; and quantify key knock-on effects based on evidence collected from businesses directly, in so far as was possible.

A four-part, 83-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 and/or reformulation; investments; expenditures; and employment) over at least 10 years from adoption of changes to the GRA and CLP.

[39] Ibid footnote 30
[40] 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)
This study also covers products in the following categories which include fragrances, PCU, PC0, PC39, PC28, PC19, PC29, PC3, PC35, PC26, PC14, PC1, PC8, PC27, PC20, PC15, PC21, PC31, PC51

- Part 4, collecting information on other economic and social 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 2-7.

Table 2-7: Types of questions covered by the economic impact survey

Policy, key business impacts or proxies	Information sought by the survey (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 fragrances sold, number of products, and gross operating profit; 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 • Percentage (or sales value) of the affected portfolio that would be in scope for substitution and/or reformulation; expected pass through of potential regulatory burden; considerations of customer responses from price changes based on historical evidence
OPEX	• 2019 turnover and tonnes of fragrances sold; 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, across different cost categories. Detailed questions associated with administrative burden from CLP especially were also considered in detail
CAPEX	• 2015-2019 average annual 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, across different cost categories
R&D	• Level of operating expenditure/ capital investment devoted to R&D expenditure 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 expected 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 i, 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 extent to which they may pass through additional regulatory burden costs to their customers
- The responsiveness of their customers to price changes

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 IFRA members and affiliated upstream partners , 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 to 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 fragrance 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.

Data was shared with Ricardo via an encrypted file sharing platform. Access to the data provided by each respondent was accessed by Ricardo only and could not be accessed by any third party or IFRA. It should also be noted that confidential data collected by Ricardo for the report was duly aggregated and anonymised, and none of the confidential information was shared between or with participants, or with IFRA.

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 fragrance 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 considering expected business responses such as substitution and/or reformulation, 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 businesses 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)
- **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 impacts. This weighting is based on the number of harmonised classifications that have been granted since 2015, the outcomes of ED and PBT/vPvB assessments, the grouping approach utilised in the 2021 ECHA Integrated Regulatory Strategy report[41] and expert judgement on the reliability of sources used in the compilation of the List of Substances to be Regulated. More detail can be found in Annex 5.
- **Extrapolating these impacts to the EU fragrance sector** , which generally included adjusting sample impacts based on the sample-to-population relationships and applying these percentage changes to the estimated EU Fragrance Sector baselines, as appropriate (e.g., annual percentage changes on the sample's turnover of X%, adjusted based on the sample-to-population relationship to Y%, and applied these adjusted Y% changes to the EU fragrance 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 fragrance 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. Further details are provided in Annex 5.

[41] ECHA (2021) *Transparent progress in addressing substances of concern.* Integrated Regulatory Strategy Annual Report. DOI: 10.2823/506792

2.7 Limitations and quality assurance

Limitations to the analysis of impacts and quality assurance (QA) used in the study are outlined in more detail below. Further details are also provided in Annex 5.

2.7.1 Limitations

The key limitations of the impact assessment analysis and associated implications are presented in Table 2-8.

Table 2-8: Key limitations of the impact assessment analysis

Limitation	Implication
CSS policy proposals remain uncertain and under development	Policy details are not yet clear, and assumptions have been required. Policy assumptions have been quality assured to ensure they reflect the current 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.
Limitations of the available data	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. However, the sample also disproportionally represents large firms in terms of turnover, to the point that the sectoral output of large companies in the sector is statistically representative of their turnover with a margin of error of +/- 5% (Section 2.5), but fails to accurately represent SMEs. Thus, 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.
Policies under consideration will affect the EU fragrance sector in multiple and complex ways	This study has limitations by design, in that it is focussed on fragrance sector business impacts and associated knock on-effects (excluding other social and environmental, as well as economic impacts driven by other dynamics outside of the fragrance sector). In this context, two key impact drivers of impact on businesses were considered: direct and indirect restrictions of use or manufacture of substances or mixtures; and additional regulatory burden, thus potentially affecting the economic viability of certain operations. The extent to which these impacts affect upstream and downstream sectors and businesses, and how these businesses may respond, will vary, including whether or not 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. Therefore, an informed simplification of the impact pathway, based on the project team expertise, was introduced, with inherent limitations. The analysis, therefore, assumes that changes to the GRA may lead to further restrictions. These restrictions would lead to the discontinuation of the use and/or manufacture of the affected products unless they can be substituted or reformulated. These business responses are expected to result in additional costs, when compared to the baseline, albeit it is assumed that they would be economically viable (given the information that was collected via survey). Changes to CLP are assumed to lead, directly, to an increase in regulatory burden, which could affect the economic viability of some operations. This is expected to be limited, and not quantified. 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 to 25% of the product portfolio affected by CLP changes, and are expected to lead to the discontinuation of the use and/or manufacture of these products unless they can be substituted or reformulated. In reality, the changes to CLP may lead to a higher or lower percentage of portfolios being discontinued. Moreover, there are also a number of known unknowns, such as how technological progress may affect the EU fragrance sector and whether and how this would interact with the impacts of legislation. These are further sources of uncertainty. Although an estimate of how grouping may expediate regulatory action has been included in the weighting of

Limitation	Implication
	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.
Substances produced under 1 tonne	This study does not capture a significant amount of the fragrance industry's portfolio, which are the fragrance materials produced in small volumes under 1 tonne. This is due to availability of information on these substances and the methodology used for the creation of the List of Substances to be Regulated.

These, and other assumptions, offer a workable and reasonable approach to assessing impacts of the policy options considered, albeit with limitations. Further assumptions and limitations are outlined in Annex 5.

2.7.2 Quality Assurance

The approaches used to assure the methodology, analysis and outputs throughout the project (including with experts within the project team) are presented in Table 2-9.

Table 2-9: Approaches taken to quality assurance

Impact assessment element	Quality assurance approach
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 consider 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 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 and carried forward into this assessment. 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 IFRA and their members 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. Feedback was requested and 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 was 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 assessment element	Quality assurance approach
Impact analysis	The project team carried out an analysis of selected impact categories, relying primarily on the data collected by consulting IFRA members and affiliated partners upstream. 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 hypotheses and, where potential issues were identified, a more in-depth review was carried out to ensure the analysis was effectively developed.

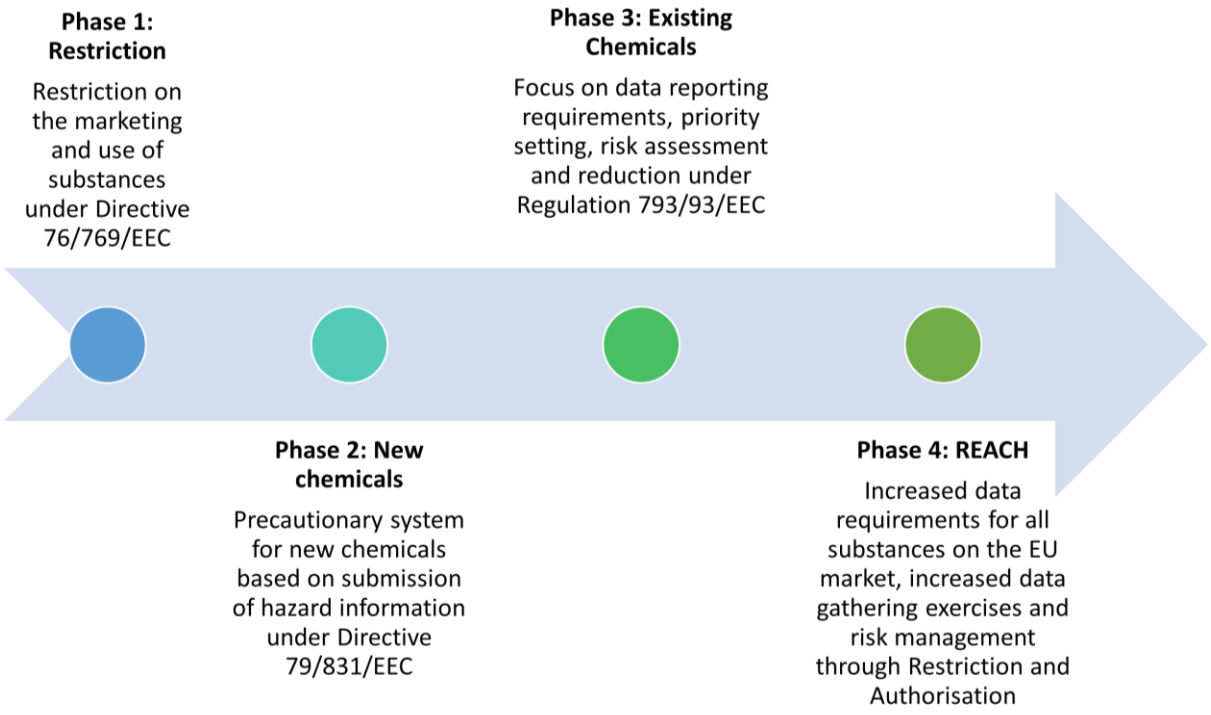
Using this quality assurance approach, the assessment and outputs presented in this report have, therefore, been reviewed and checked by a number of experts and represents an informed view of the potential impacts of the policy options considered, caveated by the limitations outlined and inherent to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

3 Context and Baseline Scenario

3.1 General Policy Context

Fragrances are found in thousands of consumer products and are complex mixtures that give products their unique scent. 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 taking 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[42]



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)[43]; Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of hazardous substances (CLP)[44]; sector specific legislation such as the Directive 2009/48/EC on Toy Safety[45], Regulation (EC) No. 1223/2009 on Cosmetics Products[46], Regulation (EU) No. 528/2012 on Biocidal Products[47], and Regulation (EC) No. 1107/2009

[42] 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
[43] 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)
[44] Ibid footnote 36
[45] *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
[46] *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
[47] *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

on Plant Protection Products[48]; health and safety of workers such as the Directive 98/24/EC on chemical agents at work[49]; and environmental protection legislation such as the Directive 2008/98/EC on Waste[50] and Regulation (EU) No. 649/2012 concerning the export and import of hazardous chemicals[51].

The REACH Regulation and CLP Regulation are the overarching pieces of chemicals legislation and have introduced different regulatory management measures for substances, mixtures and, in the case of REACH, articles, which display a range of hazardous properties. More restrictive risk management is employed for those which are deemed to be of highest concern. Recent regulatory reviews have noted that, despite the increased regulatory management of hazardous substances, more needs to be done in order to ensure a high level of protection to human health and the environment[52,53,54,55,56]. Evidence of this can be found in human biomonitoring studies in the EU which have 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.[57]

3.1.1 The European Green Deal and the Chemicals Strategy for Sustainability

The European Green Deal[58] 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*"[59]. 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 3-2.

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[48] *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

[49] *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

[50] *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

[51] *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

[52] 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

[53] Ibid footnote 32

[54] Ibid footnote 33

[55] Ibid footnote 34

[56] 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

[57] Ibid footnote

[58] 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

[59] Ibid footnote

Figure 3-2 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*"[60]. 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.

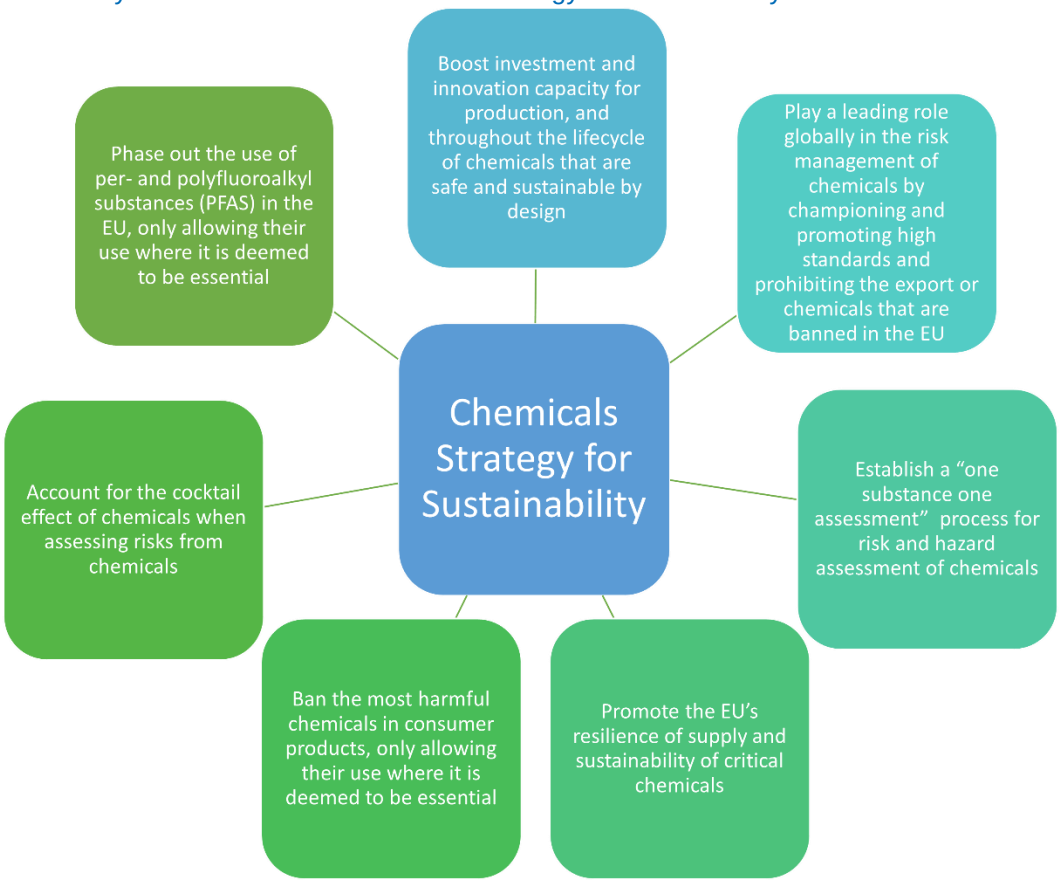
With the EU Commission's Chemicals Strategy for Sustainability comes a new long-term strategy for European chemicals policy. It is considered to be the first step in meeting the zero-pollution ambition for a toxic-free environment outlined in the EU Green Deal and is complementary to other European and Green Deal strategies and initiatives, such as the hydrogen, methane and pharmaceuticals strategies; the biodiversity and the farm to fork strategies; the Circular Economy Action Plan 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.[61]

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

[60] Ibid footnote 58
[61] 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 3-3 Key Actions of the EU Chemicals Strategy for Sustainability



Central to meeting the aims of the CSS is innovation for green transition in the chemicals industry and its value chains e.g. fragrances. 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. In order to stimulate innovation, there must be regulatory and non-regulatory incentives (e.g. financial) to ensure the EU fragrance 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.[62]

The Fragrance industry is committed to defining and ensuring the sustainability of the sector, with IFRA, in collaboration with the International Organization of the Flavor Industry (IOFI), introducing a Sustainability Charter in 2020. This Charter takes a life-cycle approach and focuses on five main areas:

- Responsible sourcing throughout the value chain;
- Reducing the industries' environmental footprint to address climate change;
- Enhancing the wellbeing of employees and ensuring a rewarding labour environment;
- Leading the way for product safety;
- Being a transparent and reliable partner for society.[63]

The first Sustainability Report has found that 75% of respondents to the survey carried out on the progress of the Charter, representing more than 90% of the fragrance and flavours market by market

[62] Ibid footnote 30
[63] IFRA-IOFI (2021) Sustainability Report: 2020-2021. Available at: https://img1.wsimg.com/blobby/go/08936067-0484-4fc2-b053-2e9fc55878d4/downloads/FINAL%20IFRA-IOFI%20Sustainability%20Report%202020-21.pdf?ver=1634631919077

share, have implemented a global environmental strategy, which implements eco-design measures in an effort to reduce consumption and waste. These strategies include waste roadmaps, implementing new business practices to reduce energy and water consumption, greenhouse gas emission and waste. Green chemistry is also an emerging practice in the Fragrance industry, that is being promoted and encouraged and is hoped to contribute towards establishing safe and sustainable by design products.[64]

Product safety is a key requirement for fragrances. 45% of respondents to the survey for the Sustainability Report indicated that they systematically engage with customers to improve the health and safety impacts of their products throughout the product lifecycle.[65]

3.2 Policy Context Specific to Classification, Labelling and Packaging

3.2.1 Implementation of UN GHS by CLP Regulation

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[66]. 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 classification and labelling of diverse preparations and mixtures of chemicals.[67]

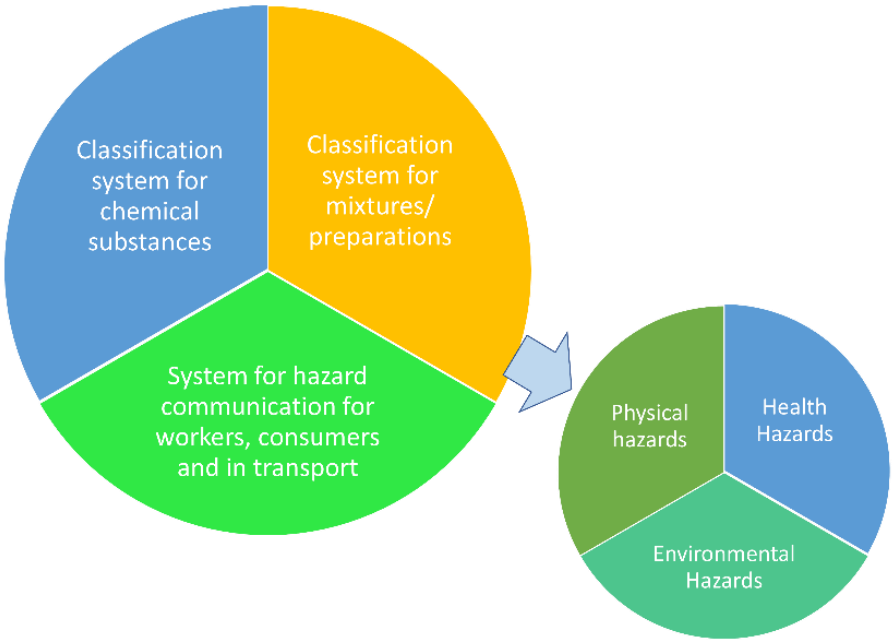
As a result of the extensive global trade in chemicals and the need to develop national programmes ensuring the safe use, transport and handling of chemicals by emergency response teams that were harmonised globally, the UN GHS was implemented by the United Nations (UN) in July 2003, with the World Summit on Sustainable Development encouraging governments to implement the new system as soon as possible (with a view to it being fully operational by 2008).[68]

The UN GHS has allowed for 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 previously.[69]

The UN GHS is based on a building block approach which provides participating countries with the hazard classes and categories from which they can form their regulatory approach to hazard classification and communication.[70] The GHS consists of three main elements, which are merged into one globally harmonised system, covering three main hazard groups (Figure 3-4).[71]

[64] Ibid 63
[65] Ibid 63
[66] UK Health and Safety Executive. (n.d.) *Background: Globally Harmonized System (GHS).* Available at: https://www.hse.gov.uk/chemical-classification/legal/background-directives-ghs.htm
[67] European Commission. (n.d.) *Classification and labelling (CLP/GHS).* Available at: https://ec.europa.eu/growth/sectors/chemicals/classification-labelling_en
[68] Ibid footnote 66
[69] United Nations Economic Commission for Europe (UNECE). (n.d.). *About the GHS*. Available at: https://unece.org/about-ghs
[70] 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 at: https://www.scielosp.org/pdf/aiss/2011.v47n2/126-131/en
[71] United Nations Economic Commission for Europe (UNECE). (2011). *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*. Available at: https://unece.org/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf

Figure 3-4 Main elements and hazard groups of the UN GHS



3.2.2 EU adoption of UN GHS

The European Union's current CLP Regulation aligns the EU system of hazard identification and classification of chemicals substances and mixtures with the UN GHS. The primary aim of the CLP Regulation is to ensure a high level of protection to human health and the environment, as well as the free movement of substances, mixtures and articles within the single market. In order to reach this aim, CLP seeks to determine whether a substance or mixture displays the properties that may lead to a classification. The Regulation establishes:

- Rules for the hazard classification of chemicals;
- How these hazards are communicated through labelling, such as through pictograms, hazard and precautionary statements, and other elements, and
- How the chemicals are packaged[72].

Under the building block approach, different jurisdictions have chosen which UN GHS hazards classes and categories to implement through their own regulations. The building blocks selected by the EU are implemented by the CLP Regulation and can be summarised as outlined in Table 3-1[73] :

Table 3-1 GHS building blocks adopted by the EU

Physical Hazards	Human Health Hazards	Environmental Hazards
Unstable explosives	Acute toxicity, Cat. 1 – Cat. 4	Acute hazards to aquatic environment, Cat. 1
Explosives, Div1.1 - Div1.6	Skin corrosion/irritation, Cat. 1, 1A, 1B, & 1C, 2	Long-term hazards to the aquatic environment, Cat. 1 - Cat. 4
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)	Respiratory Sensitisation Cat. 1, 1A, & 1B	
Flammable gases, Cat. 1A (Chemical Unstable gases, Cat. B)	Skin Sensitisation, Cat. 1, 1A, & 1B	

[72] Ibid footnote 70
[73] Ibid footnote 71

Physical Hazards	Human Health Hazards	Environmental Hazards
Aerosol, Cat. 1 - Cat. 3	Germ Cell Mutagenicity, Cat. 1A, 1B, & 2	
Oxidizing gas	Carcinogenicity, Cat. 1A, 1B, & 2	
Gases under pressure, Compressed, Liquified, Refrigerated liquified, & Dissolved	Reproductive toxicity, Cat. 1A, 1B, 2, & Lactation	
Flammable liquids, Cat. 1 – Cat. 3	STOT Single exposure, Cat. 1 - Cat. 3	
Flammable solids, Cat. 1 - Cat. 2	STOT Repeated exposure, Cat. 1 - Cat. 2	
Self-reactive substances or mixture, Type A - Type G	Aspiration hazard, Cat. 1	
Pyrophoric liquids		
Pyrophoric solids		
Self-heating substances or mixtures, Cat. 1 - Cat. 2		
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 1 - Cat. 3		
Oxidizing liquids, Cat. 1 - Cat. 3		
Oxidizing solids, Cat. 1 - Cat 3.		
Organic peroxides, Type - Type G		
Corrosive to metals		
Oxidizing solids, Cat. 1 - Cat 3.		
Organic peroxides, Type - 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[74]. However, substances with hazardous properties that were not part of the building blocks which were adopted may still be included in the Classification and Labelling Inventory (CLI).

With regard to transition times for the adoption of revisions of the UN GHS, the EU has thus far been able to fully adopt and implement changes made at the UN level into CLP. Under the implementation of the Adaptations to Technical Progress (ATPs) through the CLP Regulation, actors in the supply chain have a transition period of 18 to 24 months to respond to changes in classification and labelling[75,76]. However, according to the targeted consultation performed as part of the Fitness Check on Chemicals Legislation (excluding REACH)[77], hereafter referred to as the Fitness Check, companies had cited difficulties in complying with this period, particularly due to large product portfolios in which large numbers of products may be impacted by changes. EU Member States have concluded that the transition times appear to be appropriate with regards to both the implementation of minor editorial changes as well as the introduction of new hazard categories. However, as part of the Fitness Check (2017) consultation, they also stressed the fact that SMEs might encounter difficulties in remaining up to date with regards to the overall process and timing of when changes have to be implemented[78]. An 18-to-24-month period may be sufficient for products higher up the supply chain but may not be long enough for downstream users who need to make labelling changes, particularly where supply chains

[74] Ibid footnote 36
[75] European Commission. (2016). EU aligns its chemicals classification, labelling and packaging regulation to the 5th revision of UN GHS. Available at: https://ec.europa.eu/growth/content/eu-aligns-its-chemicals-classification-labelling-and-packaging-regulation-5th-revision-un-0_en
[76] Ibid footnote 32
[77] Ibid footnote 32
[78] Ibid footnote32

are complex and involve products consisting of mixtures within a mixture. This is a consideration that needs to be made if new hazard classes are added to the CLP Regulation.

The UN GHS states that "*consistent with the building block approach, countries are free to determine which of the building blocks will be applied in different parts of their systems. However, where a system covers something that is in the GHS, and implements the GHS, that coverage should be consistent. For example, if a system covers the carcinogenicity of a chemical, it should follow the harmonised classification scheme and the harmonised label elements… As long as the hazards covered by a sector or system are covered consistently with the GHS criteria and requirements, it will be considered appropriate implementation of the GHS*"[79].

Under the UN GHS, hazard classes are considered building blocks and within a hazard class, each hazard category is a building block. Despite competent authorities not needing to apply all hazard categories, the classification criteria of a hazard category should not be altered. Neurotoxicity is built into the building blocks for STOT RE and STOT SE, where "*attempts should be made to determine the primary target organ/system of toxicity and classify for that purpose, e.g. … neurotoxicants*"[80]. This means that the introduction of neurotoxicity as a hazard class on its own would contravene point 1.1.3.1.5.4 (b) (i) of the UN GHS.

Endocrine disruption, PBT, vPvB, and PMT, are currently neither building blocks on their own nor a hazard category within a hazard class building block of the UN GHS. This means that although the introduction of these hazard classes in CLP would be a divergence from the UN GHS approach to hazard classification and communication, it is not a contravention. Comments to the CARACAL from Cefic noted that it is their understanding that new or modified hazard classes being introduced via CLP without prior discussion at the United Nation's level could cause a global market distortion and goes against WTO rules for Member States to not create non-tariff trade barriers[81].

3.3 Policy Context Specific to Current Generic Risk Approach

In 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 risk approach (GRA) or generic approach to risk management [82]. Both risk assessment methods aim to ensure a high level of protection to human health and the environment, but they differ in their steps to achieve this goal.

The publication of the Chemicals Strategy for Sustainability (CSS) on 14 October 2020 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)* [83].

This approach is used across the breadth of the EU's chemicals legislation and is seen as reflective of the precautionary principle. The principal has been a reoccurring influence in the development of the

[79] United Nations (2011) *Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Fourth Revised edition.* Available from: https://unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf
[80] Ibid
[81] Cefic (2021) Cefic comments on CARACAL-38 presentation CLP revision V2.
[82] 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*
[83] European Commission. (2020). Chemicals Strategy for Sustainability Towards a Toxic-Free Environment (COM (2020) 667)). Available at: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

EU's Chemical Legislation for more than twenty years[84]. When applied the precautionary principle aims to produce swift reactions 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 the substance is widely used. In 2000 the Commission stated that measures as a consequence of the precautionary principle must be:

- "*Proportional to the chosen level of protection,*
- *Consistent with similar measures already taken,*
- *Based on an examination of the potential benefits and costs of action or lack of action,*
- *Non-discriminatory in their application,*
- *Subject to review, in the light of new scientific data,*
- *Capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment."*[85]

Measures aligned with these properties can be implemented with speed to counter possible risks to human health or the environment. The properties above are important to the responsible use of the precautionary principle as in-depth assessments are not required to support the consequential risk management measures[86].

Building on from the precautionary principal, the GRA selects chemicals for regulatory action based on the substance's intrinsic properties (e.g. Carcinogens, mutagens and reprotoxicants (CMR), Persistent, Bioaccumulative and Toxic (PBT), Endocrine Disruptor (EDs) etc.), without the need, or possibility, to assess and account for risk as a result of exposure to the substance of concern[87]. Many chemicals are known to cause serious damage to human health and the environment[88] and an increase in certain health problems have been partially attributed to the exposure to these chemicals[89]. To provide rapid protection from specific risks, automatically triggered risk management measures are enforced under the GRA. Within EU chemicals policy, the GRA is an example of a preventative action[90]. This 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.

In contrast, Specific risk assessments (SRAs) require hazard identification in combination with a use and potential exposure assessment before regulatory action can take place[91].

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'*[92]

SRAs are performed on a case-by-case basis[93]. 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 less of a concern[94]. The simultaneous considerations of the substance's physical and chemical properties as well as intended use, aims to account for how these properties may increase or decrease the substance exposure and therefore, more appropriately assess the risks.

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[84] Ibid footnote5433
[85] European Commission, 2000, *Commission adopts Communication on Precautionary Principle, [Online] Available from: https://ec.europa.eu/commission/presscorner/detail/en/IP_00_96*
[86] Herzler, M., Marx-Stoelting, P., Pirow, R. et al. The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence? Arch Toxicol 95, 2589–2601 (2021). https://doi.org/10.1007/s00204-021-03091-3
[87] Ibid footnote 82
[88] European Commission, 2020. *Chemicals are everywhere.* [Online] Available at: https://ec.europa.eu/environment/chemicals/index_en.htm
[89] Ibid footnote 56
[90] Ibid footnote 8282
[91] ChemSec, 2020. *5 aspects that the Chemicals Strategy must include.* [Online] Available at: https://chemsec.org/app/uploads/2020/04/Chemicals-strategy-ChemSec-view-April-2020.pdf
[92] Ibid footnote 83
[93] Ibid footnote 82
[94] Ibid footnote 82

EU chemicals legislation incorporates the specific approach in two main ways: [95]

- *Leading to 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.
- *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 the need to limit the substance concentration or restrict certain uses.

Table 3-2 Scenarios for application of Generic Risk Approach and Specific Risk Assessment

Generic Risk Approach	Specific Risk Assessment
• 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. • 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.	• Typically applied to substances where the hazard properties of the substance are of lesser concern; and/or • whose use may not necessarily or obviously lead to widespread and difficult to control exposures.

3.3.1 Comparison of Risk Management Measures

The two approaches (GRA and SRA) 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 the hazard classification has been applied, thus producing a streamlined risk management approach. This speed is deemed necessary in the scenarios where the GRA is 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. The SRA approach does not make generalisations regarding exposure and the assessment covers the substance use and possible exposure routes in detail. Exposure 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. Nevertheless, the outcome for many substances of high concern, 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.

Both approaches are enforced across the breadth of chemical legislation, and there are many examples where individual pieces of chemicals legislation that 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

[95] Ibid footnote 33

and 2*. The rationale being that direct exposure of humans is occurring by the application of a cosmetic product.[96]

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. [97]

*subject to strict derogations

The Fitness Check (2017)[98] and the Fitness Check+ (2017)[99] discussed the key advantages and drawbacks associated with the GRA and SRAs. The differences in approach have been summarised below in Table 3-3.

Table 3-3: Comparison of advantages and disadvantages 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 outcome of the risk management decision making process is more predictable (compared to SRA) • 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 which helps to protect human health and the environment in a timely manner.	• Allows for a more targeted assessment of the exposures and thus risks according to the intended use, reducing over-regulation of substances. • Considerations of the products physico-chemical properties contributes to a more appropriate identification of exposure and of risk management measures. • Generally considers socio-economic assessments to understand 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 +")

[96] Ibid footnote 82
[97] Ibid footnote 82
[98] Ibid footnote 82
[99] Ibid footnote 33

3.3.2 Current Approach

3.3.2.1 Legislation currently affected

The current breadth of EU chemicals legislation means the two risk management approaches, covered previously, are included under specific legislation which each have their own reference to the GRA and/or SRAs.

The fragrance industry must comply directly with Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) but will also be influenced by specific legislation pertaining to the final use of the fragrance product. These commonly include Regulation (EC) No 1223/2009 on cosmetic products, Regulation (EC) No 648/2004 on detergents and Directive 2009/48/EC on the safety of toys. In addition, when the fragrance compound contains a preservative Regulation (EU) No 528/2012 biocidal products is also of relevance.

In the 2017 Fitness Check, the possible risk management measures following classification according to the CLP Regulation were investigated. Four possibilities were defined in the report, these possibilities align with the GRA, the GRA with derogation, 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. The relevant regulations to the fragrance industry from the Fitness Check have been presented in Table 3-1Table 3-1 with the addition of REACH.

Table 3-1: Overview of the inclusion of GRA, SRA and further implementation measures in different pieces of consumer, professional and occupational safety & health (OSH) EU chemicals legislation.

	Legislative Act	GRA	GRA with derogation	SRA	Further implementation
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals	X	x	x	x
Consumer	Regulation (EC) No 1223/2009 on cosmetic products	X	x	x	
	Regulation (EC) No 648/2004 on detergents			x	
	Directive 2009/48/EC on the safety of toys	X	x		
Professional	Regulation (EU) No 528/2012 biocidal products	X	x	x	x

Source: 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 at: https://op.europa.eu/en/publication-detail/-/publication/7e26e205-18f9-11e7-808e-01aa75ed71a1

The use of certain fragrances in cosmetic products, toys and detergents is already restricted or banned due to allergenic properties. The risk management measures currently applied to fragrance allergens align with the specific risk management approach, requiring specific assessments and leading to substance restriction. The specific risk assessments can be triggered by industry or by a Member State through a safeguard clause[100]. These fragrances are then assessed by the relevant Scientific Committee, identified as an allergen, and added to the respective list. For toys this list can be found under point 11, Part III of Annex II (Particular Safety Requirements) to Directive 2009/48/EC on toy safety. For cosmetic products and detergents, the list can be found under Annex III of Regulation (EC)

[100] Ibid footnote 33

No. 1223/2009 on cosmetic products. This list was first established by the Scientific Committee on Cosmetics and Non-food Products (SCCNFP) and has been developed by the Scientific Committee on Consumer Safety (SCCS) [101].

Fragrances must also comply with Article 68(2) of REACH, which restricts the use of CMR cat. 1A and 1B substances in products for sale to the general public, and the generic restrictions of CMR substances under both the Cosmetic Products Regulation (Article 15) and Toy Safety Directive (Annex II, part 3).

3.3.2.2 Current Risk Management Difficulties

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[102]. A consistent approach could 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 SRA, as well as the numerous different derogations applied in combination with the GRA across the current EU chemicals legislation[103].

Fragrance products are highly dependent on the outcomes of SRAs by the Scientific Committee on Consumer Safety (SCCS). The outcomes of these assessments are less predictable and can result in the restriction or prohibition of the fragrance in certain products. The SCCS also has a strong role to play in the identification and consequential risk management of fragrance allergens. The SCCS provides a clear definition for “contact allergy” and the most extensive list of contact allergens, this information is beneficial to the industry[104]. The IFRA Safe Use Programme also covers skin sensitisers and fragrance allergens, and provides guidance on recommended assessments for identification. However, sector specific legislation is currently not as clear with respect to the term “allergen”. For example, neither the Cosmetic Products Regulation nor the Toy Safety Directive specifically define the term in spite of both pieces of legislation requiring actions based on this property[105][106]. In addition, the collection of fragrances labelled as allergenic can vary depending on the specific piece of legislation, as well as the method for communicating this property. The Toy Safety Directive specifically lists 65 allergenic fragrances and the required risk management measures, whereas the Cosmetic Products Regulation states the allergenic properties of certain substances under the warnings in Annex III and requires the labelling of 26 fragrance allergens. These differences have been noted by stakeholders outside of the fragrance industry, specifically by Member State Authorities [107].

Many also argue that the GRA is an inappropriate or disproportionate approach for certain substances. By initiating restrictions based on hazards only, it is possible for substances to be banned without an evaluation on the routes of exposure. Consequently, because a risk assessment is not required, the measures are purely hazard initiated and have been considered proportionate only when exposure to a hazard can be predicted[108]. Proportionality is an important factor in risk management but this, alongside exposure routes, is not a direct consideration of the GRA. By focusing solely on hazards, chemicals, which are valuable to society and have minimal exposure routes in certain applications, may be banned[109]. This in turn will negatively affect the overall aim of protecting human health and the environment. Further to this, the substitution of a substance restricted via the GRA could lead to the use of lesser known, harmful chemicals, so called “regrettable substitution”[110].

[101] European Commission 2004. REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Detergents
[102] Ibid footnote 82
[103] European Commission, 2021. *Inception Impact Assessment - Ares(2021)2962933 - Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals*
[104] European Scientific Committee on Consumer Safety, 2012, Allergenic fragrances in cosmetic products, [Online] Available from: https://ec.europa.eu/health/sites/default/files/scientific_committees/docs/citizens_fragrances_allergens_en.pdf
[105] Ibid footnote 46
[106] Ibid footnote 45
[107] Ibid footnote 33
[108] Ibid footnote 91
[109] Ibid footnote 91
[110] Ibid footnote82 82

In contrast the difficulties associated with the use of the SRAs are mainly with the process rather than the outcome. The vast data requirements are a large burden for manufacturers and government bodies. In addition, the quality of this information has been criticised. This criticism lies mainly with the modelling of exposure scenarios, as the ability to accurately assess all possible exposure scenarios of a substance is notoriously difficult[111].

3.4 Business Context and Baseline

This section outlines the main economic figures for the EU-27 fragrance industry and presents the picture of its current business context and its intricacies. Baseline projections are then presented for all variables of relevance, 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.

3.4.1 Sectoral Scope and Context

EU fragrance companies develop and produce substances and complex mixtures that are present in a wide variety of products of daily use: shampoo, soap, body wash, deodorant, body lotion, disinfectants and gels, makeup, facial cream, perfume, etc. To encompass this breadth, the scope of the fragrance industry that is going to be used throughout this document corresponds to NACE Rev. 2 Code C 20.53, which is defined as follows:

> This class includes the manufacture of extracts of natural aromatic products, resinoids and mixtures of odoriferous products for the manufacture of perfumes or food, and excludes the manufacture of synthetic aromatic products and the manufacture of perfumes and toilet preparations[112].

According to this definition, the manufacture of synthetic aromatic products contained in NACE Rev. 2 Code '20.14 Manufacture of other organic basic chemicals' would not be covered here, although a comparison between sector size, in turnover value of NACE Rev. 2 Code '20.53 Manufacture of essential oils' and the sector size in turnover value as reported by the industry[113] shows that the total size of the sector is well captured by NACE Rev. 2 Code 20.53. In particular the sector size by turnover € million was the same under both accounts. Additionally, NACE Rev. 2 Code '20.14 Manufacture of other organic basic chemicals' contains production that belongs in other sectors, and only a small and unknown share of it pertains to the fragrances industry.

This sector comprises almost 800 businesses and employs more than 19,000 people in the EU-27. In 2018, the economic output of these companies was valued at €7.6 billion per year[114], of which under a third, or €2.3 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)).

Further, between 14 and 16 large businesses, according to historical data, or 2% of the total, generate around 50% of sectoral output and employ more than 8,000 workers. The rest is generated by around 750 Small and Medium Enterprises (SMEs) that employ around 11,000 workers[115].

Extra-EU exports of the EU fragrance sector amount to €1.2 billion and represent 16% of the sector's turnover[116]. The European share of the global fragrance market has grown slightly over the past 5 years and the region is expected to continue dominating the market. Nevertheless, other regions such as South America and Asia-Pacific are also anticipated to significantly grow over the next decade[117].

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[111] Ibid footnote54
[112] Eurostat (2008). *Nace Rev.2 Statistical classification of economic activities in the European Community*. Available from: https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF
[113] PwC (2019). *A socio-economic contribution study for the global fragrance industry*. Available from: https://ifrafragrance.org/docs/default-source/policy-documents/pwc-value-of-fragrance-report-2019.pdf?sfvrsn=b3d049c8_0
[114] All monetary figures are expressed in 2020 constant euros.
[115] 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. All employment figures are expressed in FTE units.
[116] Ibid footnote 112
[117] Fortunate Business Insights (2021), *Essential oils Markets Size, Share & COVID'19 Impact Analysis. Available from: https://www.fortunebusinessinsights.com/industry-reports/essential-oils-market-101063 [Accessed 11/2021]*

A 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU chemicals industry[118] suggests that the regulatory burden affecting the sector represents over 2% of their turnover[119]. 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. In the particular case of the fragrance industry, the regulatory burden is estimated to be closer to 4% of the sector's turnover, or 44% of its Gross Operating Surplus.

Changes to the classification of substances tend to require additional investments and administrative activity from businesses, that is, they produce a regulatory burden. Although the Cumulative cost Assessment. (2016)[120] excludes regulatory costs from changes in the classification of substances, they are included in the assessment in this report.

Regulatory burden is variable across subsectors, reflecting differences in product groups and their value chains; hence the importance of including a measure of its monetary value for a particular subsector of the chemicals industry as in this report, in the context of the CSS affecting the whole chemicals industry. SMEs can also incur comparatively higher costs in some cases, due to non-linearities with respect to production volume.

3.4.2 Historical Trends and Baseline Projections

Over the last 10 years, the turnover or revenue of the EU fragrance sector has grown 7.3% per year, on average. Recently, however, the COVID-19 pandemic has had an impact on the operations of the EU fragrance sector. In 2020, the pandemic resulted in a contraction of sectoral revenue and productive output that is estimated at 10%[121]. The contraction in European economies experienced during the pandemic is expected to be rapidly overcome, according to European Commission's estimations about GDP recovery[122], with sector revenue and Gross Value Added estimated to grow 26% in 2021 and 5% in 2022 as a result. Thereafter, the sector is expected to continue on its long-term growth trend.

Over the coming decades, these key trends are expected 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 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 fragrance sector.

[118] Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission), Technopolis Group, VVA. (2017). *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
[119] 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.
[120] *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
[121] Ricardo own estimations from econometric regressions relating the output of the EU-27 fragrance sector to EU-27 GDP and population.
[122] 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

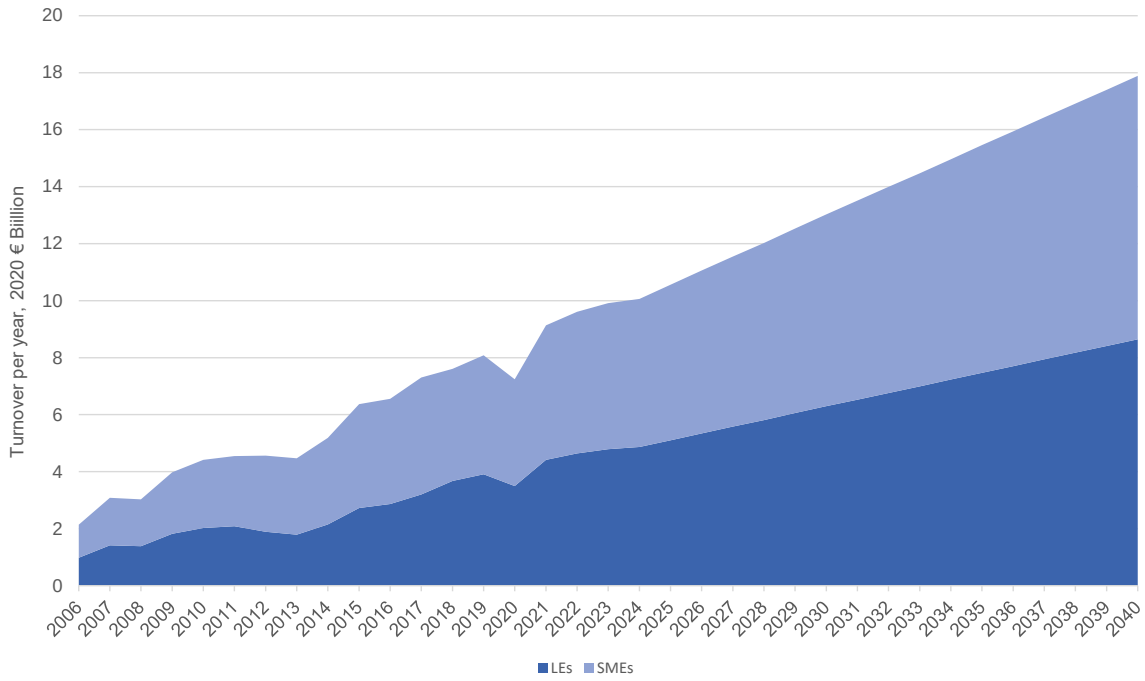
3.4.2.1 Turnover of the EU-27 fragrances sector

The EU fragrance sector's turnover is projected to grow at a Compound Annual Growth Rate (CAGR) of 3.5% over the next 20 years and is depicted in Figure 1-1 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 80% from 2023 to 2040.

Over the last decade, both large enterprises and SMEs have driven the growth of the EU fragrance sector. The turnover of larger enterprises has grown at a CAGR of 7.9% during this period, or a cumulative growth of 21%, while SMEs have experienced a similar annual growth rate of 6.8%, or a cumulative growth of 2% over the period. These trends produce a very balanced picture and dynamic between different firm sizes of the fragrance industry. As a result, SMEs are expected to continue generating half of the sector's turnover in the future.

The split of turnover, or sales, between large enterprises (LEs) and SMEs is shown below in Figure 1-1.

Figure 1-1 Total turnover and breakdown between SMEs and LEs of the EU-27 fragrance sector



Source: Ricardo analysis based on Eurostat data.

3.4.2.2 Value added of the EU-27 fragrances sector

The Gross Value Added of the fragrance 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 €2.3 billion in 2018, or around 30% of its economic output. This has increased steadily over the last decade at a CAGR of 3.9 %, which is around half the rate of the sector's output growth. Two trends have potentially contributed to this:

- Intermediate costs have grown at a faster pace than output (9.6% vs 7.3% per year) over the last decade[123].

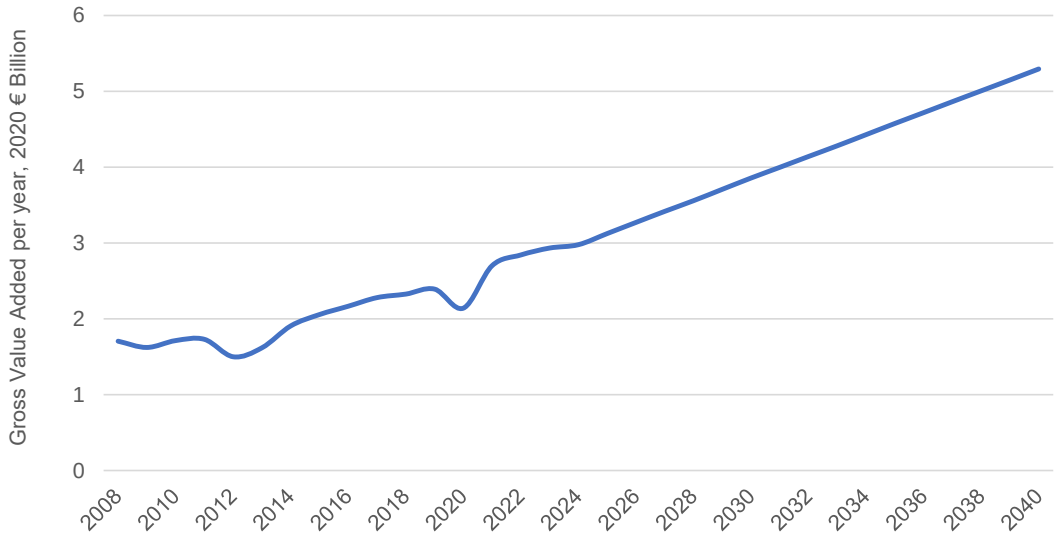
[123] Cefic (2021), *Facts and Figures*. [online] Available from: 2021 Facts and Figures of the European Chemical Industry - cefic.org [Accessed 09/2021].

- The sector's overall investment as capex has grown relatively more slowly than output (2.2% vs 7.3%). Part of this growth has allowed an energy transition for the sector, estimated to have reduced its energy intensity by 22% in the chemicals industry as a whole.

These trends were experienced by both large and smaller enterprises; however, large firms appear to have contributed relatively more to sectoral GVA growth (4.8%).

In the baseline scenario, these trends are expected to continue into the future, as shown below in Figure 3-6, with GVA maintaining its historical trend.

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



Source: Ricardo analysis based on Eurostat data

3.4.2.3 Intermediate consumption, including operating costs of the EU-27 fragrance industry

The intermediate consumption of the EU fragrance industry refers to the value of the industry's demand of "goods and services consumed as inputs by a process of production" [124]. This represents a significant proportion of operating costs of the industry as well as its interconnectedness with the local (and international) economy and its ability to drive activity through the supply chain.

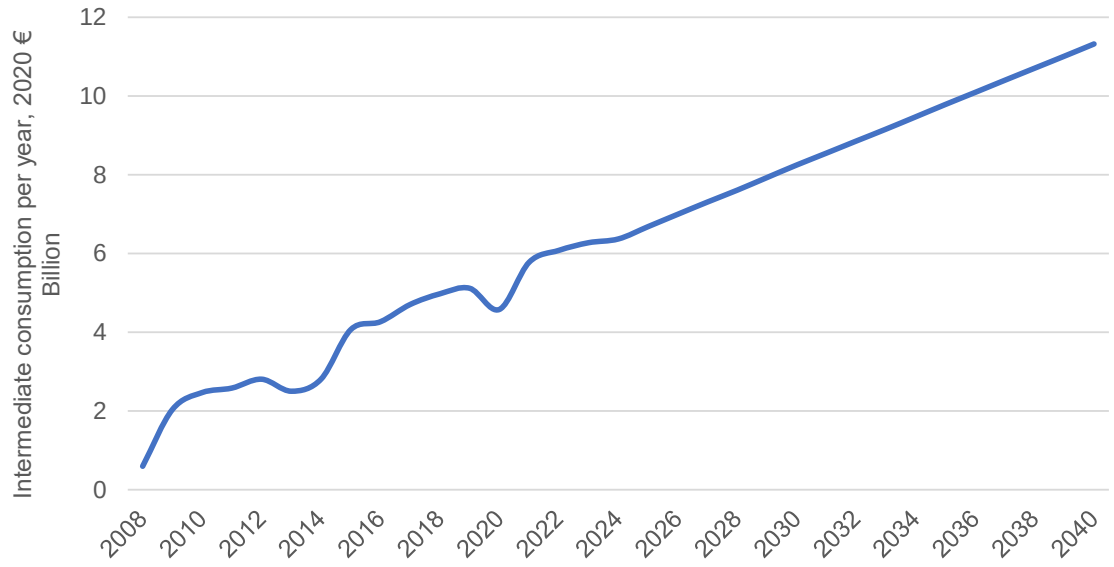
There is historical data available for this indicator at the EU-27 fragrance sector level, which has been used to produce baseline projections. These projections offer a proxy for the evolution of operational costs, whilst it is acknowledged that intermediate consumption excludes the costs of employment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

The intermediate consumption has grown at a CAGR of 9.6% in the last decade. Therefore, this means that intermediate consumption per unit of revenue has declined. A similar trend is expected for overall operating costs, possibly reflecting cost increases for upstream suppliers.

This trend is expected 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[125]. This transition will be costly and require both increasing some operating as well as capital expenditures, but in the net and although uncertain, it is expected to drive a similar level of growth in intermediate consumption and other operating costs in the baseline. At the same time, energy operating costs will be reduced, which will result in reducing operating costs per unit of revenue.

[124] Eurostat, (2021). *Glossary* [Online] Eurostat. Available from: Glossary:Intermediate consumption - Statistics Explained (europa.eu)
[125] Ibid footnote 58

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



Source: Ricardo analysis based on Eurostat data

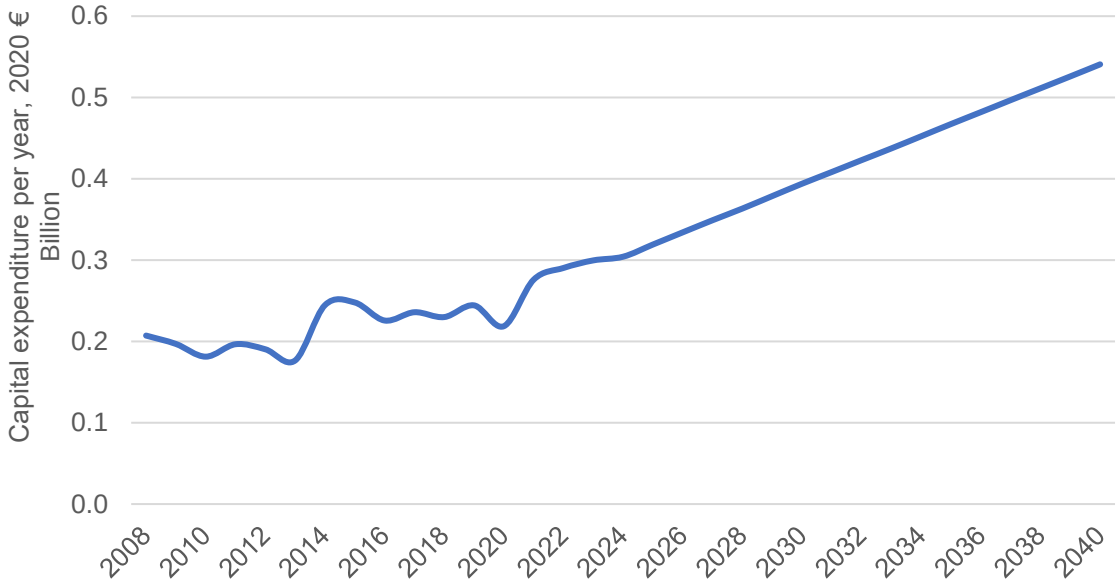
3.4.2.4 Capital expenditure activity in the EU-27 fragrance sector

Capital expenditure by the fragrance sector has generally grown in the last decade, albeit more moderately than the sector's turnover. The investment based in the EU-27 has grown at a CAGR of 2.1% from 2009 to 2019.

For the next two decades, the observed growth trend in capital expenditure is expected to continue, following turnover growth. 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 fragrance sector.

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 fragrance sector are shown in Figure 3-8 below.

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



Source: Ricardo analysis based on Eurostat data

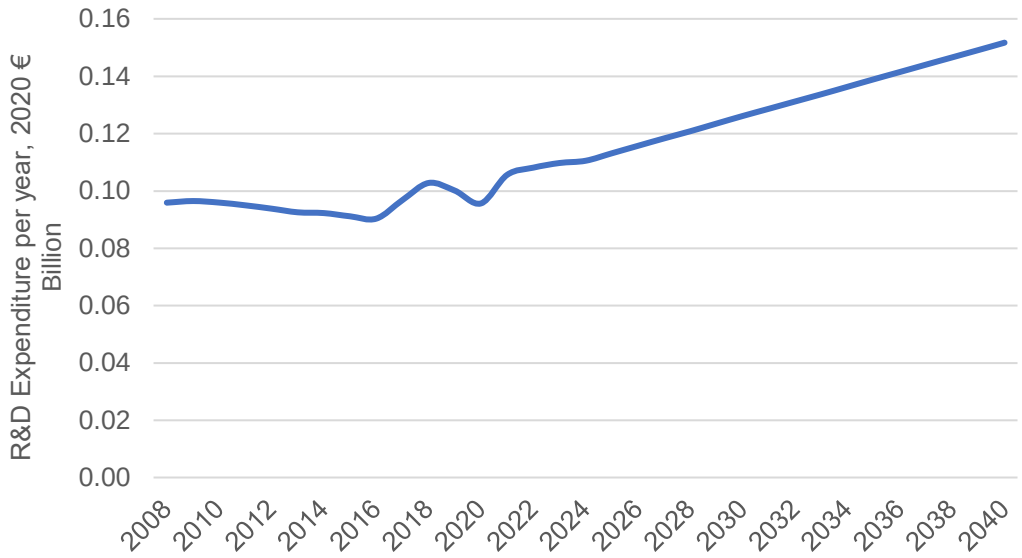
3.4.2.5 Research and Development in the EU-27 fragrances sector

According to IFRA's 2019 report[126], "*Consumer product manufacturers and retailers often rely on innovation from the fragrance industry to provide differentiation through technology, understanding of consumer trends, and sustainable production*". The report presents the proportion of net sales invested in R&D by fragrance manufacturers to be 8%.

Regarding R&D trends, expenditure in R&D by the EU fragrance sector has grown at a relatively slow 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[127], it is estimated that R&D expenditure will continue its trend of moderate growth, with 1.9% per year on average in the period of 2023 to 2040, as shown in Figure 3-9 below.

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



Source: Ricardo analysis based on Cefic data[128].

In addition to this expenditure in the EU-27, some fragrance firms also invest and/or develop some or all of their R&D activities outside of the EU. Of the companies who participated in this study, 60% of respondents develop all of their R&D activities in the EU-27, 13% develop the majority (>50%) of their R&D activities in the EU, and 23% develop less than 50% of their activities in the EU. 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.

It is also worth noting, despite R&D growing at a relatively slow rate, globally investments in R&D by the fragrance industry have been estimated as 8% of net sales, double the European Union average for large global companies[129].

3.4.2.6 Regulatory burden of the EU-27 fragrances sector

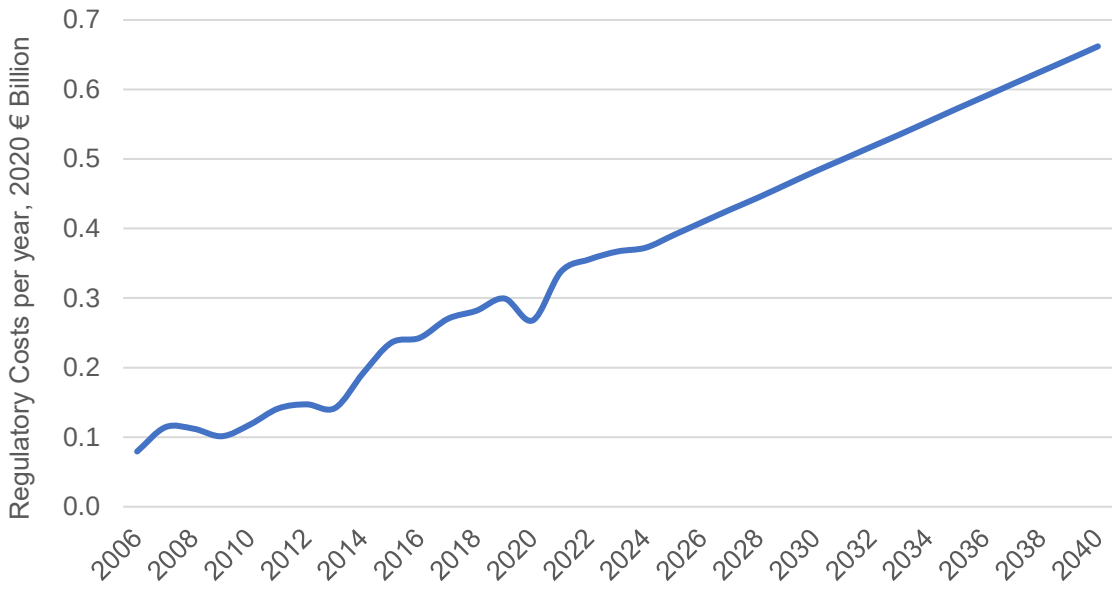
As noted earlier, the 2016 study of the cumulative costs of the most relevant EU legislation with a bearing on the EU Chemicals industry[130] suggests that the regulatory burden affecting the sector

[126] IFRA (2019), *The value of fragrance. A socio-economic contribution study for the global fragrance industry,* Available from: https://ifrafragrance.org/docs/default-source/policy-documents/pwc-value-of-fragrance-report-2019.pdf?sfvrsn=b3d049c8_0
[127] Evidence of past and expected R&D for the sector is very limited and has been complemented by the general expected trends for the sector growth.
[128] Ibid footnote 123 Note: all Cefic data used in this study is macroeconomic, historic and publicly available.
[129] IFRA (2019), *The value of fragrance. A socio-economic contribution study for the global fragrance industry,* Available from: https://ifrafragrance.org/docs/default-source/policy-documents/pwc-value-of-fragrance-report-2019.pdf?sfvrsn=b3d049c8_0
[130] Ibid footnote 120

represents over 2% of their turnover, also reported in a more recent study by Cefic[131], while for the fragrance industry, this is estimated to represent almost 4% of its turnover.

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 €0.3 billion, and this burden would be likely to grow over time in line with the expected increase in sectoral operations and associated turnover, as shown in Figure 3-10 below.

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

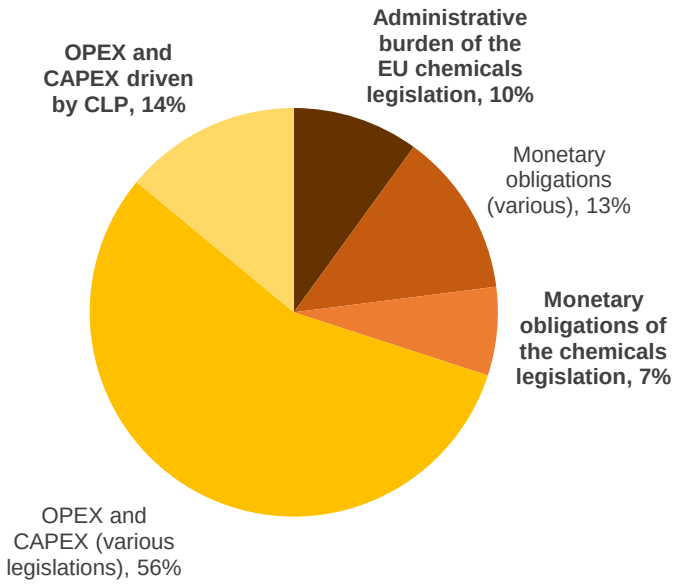


Source: Ricardo analysis based on Eurostat data and Technopolis Group, VVA. (2016).

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.

[131] Ibid footnote 123

Figure 3-11 Composition of the regulatory burden affecting the fragrance sector in the EU-27 (Regulatory burden of the categories in bold are driven by EU chemicals legislation only)



Source: Technopolis Group, VVA. (2016).

3.4.2.7 Employment

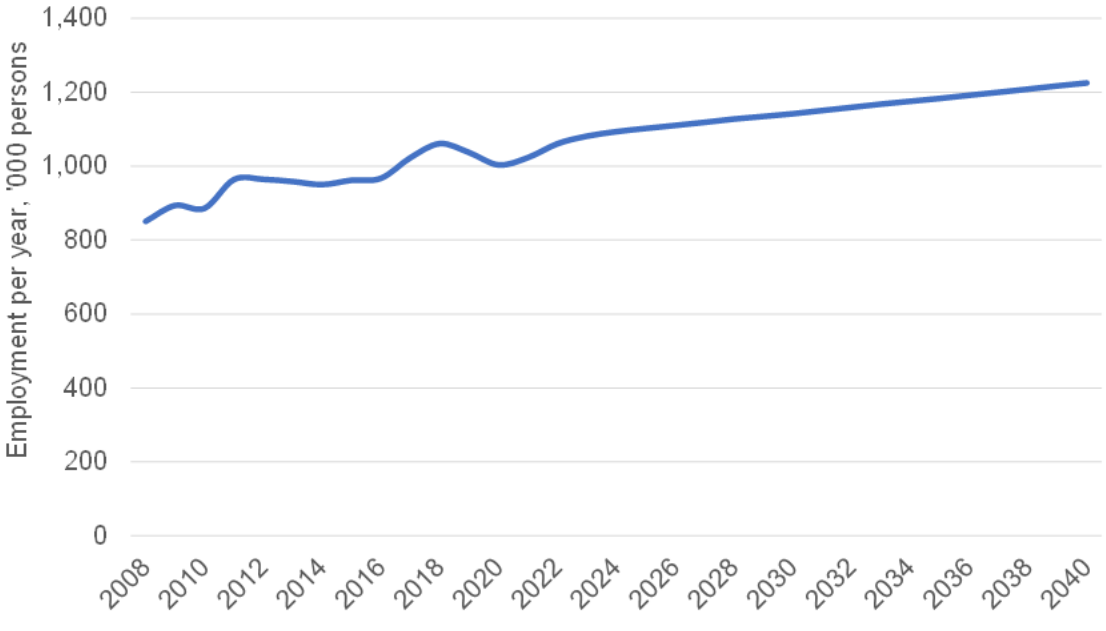
The whole chemicals industry is characterised by the employment of highly qualified professionals, who are remunerated accordingly, and the fragrance industry is not an exception. Employment compensation in the chemicals industry is among the highest, behind only petroleum refining and pharmaceuticals. According to IFRA, "*jobs in the fragrance industry are high-skilled, high-value and R&D focused, with employees in sourcing R&D, creation, evaluation, sales and manufacturing generating high Value Added*[132]".

As the EU-27 fragrance sector continues to expand in the future, this is likely to be complemented by an increase in labour demand. However, this relationship between the sector's output and employment has some particularities in that it has not been one-to-one; rather, employment in the fragrance sector has grown at a more moderate pace than industrial output and turnover. On average, employment has grown at an average 2.4% in the last decade in the fragrance industry.

Based on these considerations and trend analysis, employment is expected to continue to grow at a slower rate than turnover in the future, maintaining its past trend more in line with general macroeconomic growth, with an expected increase of 1.9% per year on average in the period of 2023 to 2040. This is shown below in Figure 3-12.

[132] Ibid footnote 126

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



Source: Ricardo analysis based on Eurostat data

Large enterprises, even though they are only 2% of all firms in the fragrance sector, represent more than 43% of the total fragrance sector employment, with around 8,000 employees. This share is expected to be, at least, maintained in the baseline scenario.

4 Policy Options

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, are presented in this section. They have been identified by the mapping and screening of the CSS actions and impacts detailed in Section 2.4. Assumptions related to potential regulatory actions that form basis for this assessment are also presented. To note, the policy options and assumptions presented in this section have been carried forward from the Cefic study[133].

4.1 Definition of the policy options considered

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 is recognised in the CSS. The CSS therefore 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[134]. It is proposed that by reinforcing the cornerstone legislation for regulation of 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 that this can be achieved.

The strategy does not include detailed guidance on the proposed implementation of the extension of the GRA. However, 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.

4.1.1 Addition of Hazards to CLP

Policy options were screened, and the shortlist presented in Table 4-1 has been carried forward in our analysis for addition of hazards to the CLP Regulation.

Table 4-1: Addition of hazards to CLP – Short-listed policy options

Policy option	Description
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.	EDCs 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. 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) and biocides under the Biocidal Products Regulation ((EU) No. 528/2012). 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.

[133] The European Chemicals Industry Council (Cefic) (2021) Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability.
[134] The European Chemical Industry Council (Cefic). (2020). *Chemicals Strategy for Sustainability*. Available from: https://cefic.org/policy-matters/chemical-safety/chemical-strategy-for-sustainability/

Policy option	Description
	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). 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, 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.
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". This will entail moving PBT/vPvBs currently covered by REACH across to 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. 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.

4.1.2 Extension of the Generic Risk Approach

Policy options were screened, and the shortlist presented in Table 4-2 has been carried forward in our analysis for extension of the Generic Risk Approach.

Table 4-2: Extension of the GRA – Short-listed policy options

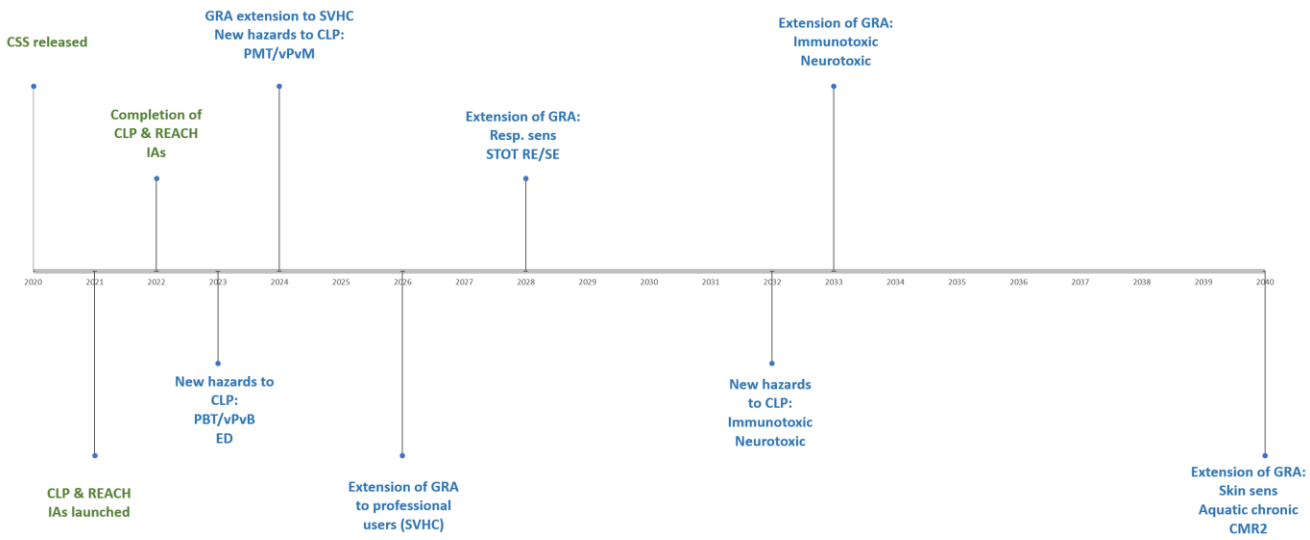
Policy option	Description
a) Extend the generic approach to risk management to ensure that consumer products – including, among other things, food contact materials, toys, childcare articles, cosmetics, detergents, furniture and textiles - do not contain chemicals that cause cancers, gene mutations, 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.	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.
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 Restrictions under 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 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 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 analysis a reasonable scenario has been developed for the GRA for consumers and professional uses. Although not certain, this scenario assumes the changes and consequences that are likely to be triggered by the CSS.

4.2 Assumptions for Analysis

This section provides an overview of the assumptions that have been developed by the study team and Cefic and carried forward in this assessment to allow for an ex-ante assessment of economic impacts. Assumptions have been based on a literature review of publicly available information. Figure 4-1 provides the phased-approach timeline that has been used in Scenario 1 of the assessment of impacts, which has been based on the Action Plan in the Annex to the CSS. It has been updated based upon expert judgement, reflecting discussion in the CARACAL and the need for Commission impact

assessments to be undertaken. The timeline below presents a phased approach for implementation that would allow industry greater opportunity to respond to regulatory change.

Figure 4-1: Implementation Timeline Used in this Study



4.2.1 Assumption 1 – Hazard Classifications of Concern

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 classify 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, 1B.
- All Skin Sensitiser substances, category 1, 1A, 1b.
- All Aquatic Chronic substances, categories 1 and 2.

4.2.2 Assumption 2 - New hazards to CLP

The EU Chemicals Strategy for Sustainability outlines the 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 4-3 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 4-3: Assumption 2 - Timeline for Addition of New Hazards to the CLP Regulation

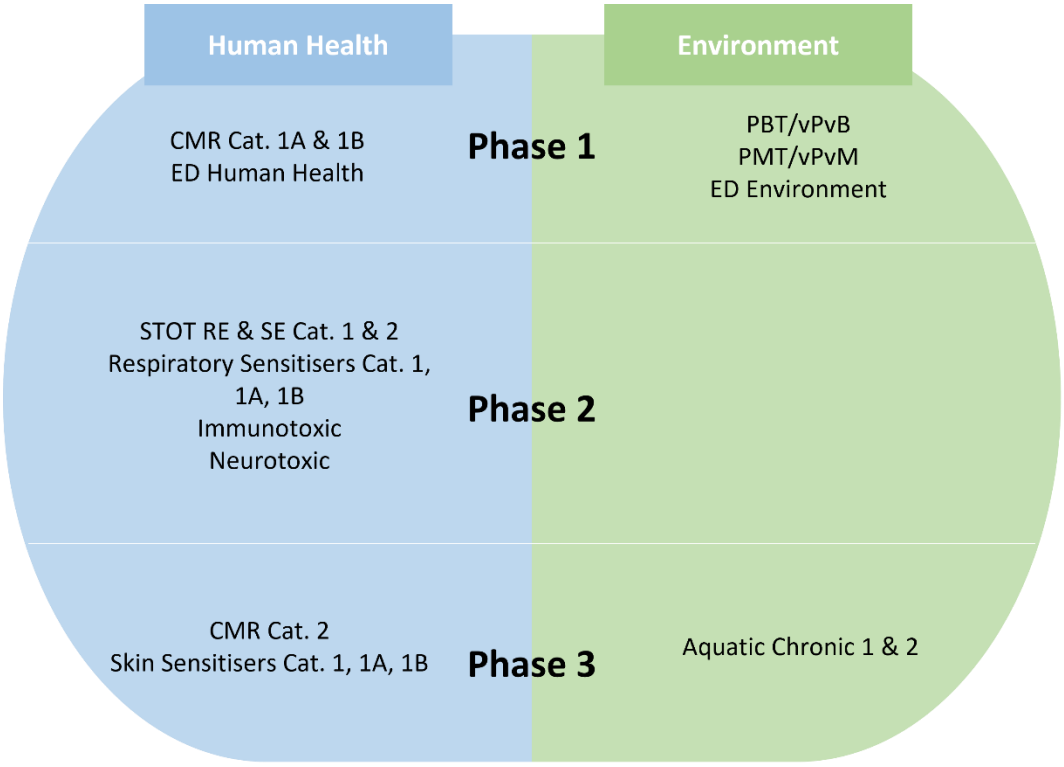
Revision	Year	Hazard Class
1	2023	ED PBT/vPvB

		PMT/vPvM
2	2032	Immunotoxic Neurotoxic

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

Figure 4-2 below provides an overview of the assumptions for the groups of hazard classes that will be included in the extension to the GRA.

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 no longer being considered "equivalent level of concern" under Article 57(f) of REACH.

The extension of the GRA may not only be limited to REACH Restriction under 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 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. It is acknowledged that the Restriction Roadmap presents the restriction of skin sensitisers most likely before the extension of the GRA and discussion with the Commission has indicated that skin sensitisers may not be included in the GRA. Should the Commission follow the hierarchy of hazard, it could be assumed that skin sensitisation would be of lower priority than respiratory sensitisers or STOT RE/SE and so for the phased implementation timeline, the restriction of skin sensitisers have been moved to 2040. These assumptions are based on

the need for completion of EU Commission impact assessment studies, adoption of new hazard classes in the CLP Regulation and entry into force of implementing acts.

Table 4-4: Assumption 2 - Extension of the Generic Approach to Risk Management

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. Implementing acts may need to be introduced to allow for the extension of the GRA in REACH and sector specific legislation. 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.

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.

As a select number of fragrance ingredients are known skin sensitisers, the inclusion of these hazard categories in the second and third phase extension of the GRA respectively is expected to impact the fragrance industry. However, these substances may have already been addressed in sectoral legislation due to being listed as an allergen. Currently under the Cosmetic Product Regulation listed allergens are subject to labelling and under the Toy Safety Directive the use of listed allergens is restricted. It should be noted that not all allergens are skin sensitisers but there is an overlap. It should also be noted these fragrance products may have hazard classifications of concern relevant to earlier phases of the extension of the GRA, e.g. endocrine disruption, therefore diffusing the impact specifically from the second and third phase of the extension of the GRA.

4.2.4 Assumption 4 – Sample representativeness

The basic underlying assumption throughout all the analysis for business impacts is that the sample of companies surveyed is representative of the whole fragrance sector. Impacts calculated from survey responses in percentage form and weighted by business size are directly extrapolated to the overall sector.

4.3 Scale of products that may be affected

The scale at which products will be affected has not been possible to be fully determined, since the CSS does not include detailed guidance on the proposed actions, and the changes that the CSS will introduce will likely impact different pieces of legislation. Annex 1 provides an overview of the changes and product sectors that are expected 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 that was created for this exercise. Figure 4-3 below 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 formulators. These companies usually buy substances from manufacturers, formulate new products which may then be sold for further formulation or to article producers, which in turn sell to end consumers. Therefore, Figure 4-3 reflects level two in the value chain. Only direct sales of respondents are considered. Data from further down the value chain was not received in this consultation, reflected by the null number of articles included.

Figure 4-3 classifications as reported by surveyed companies in the fragrances sector

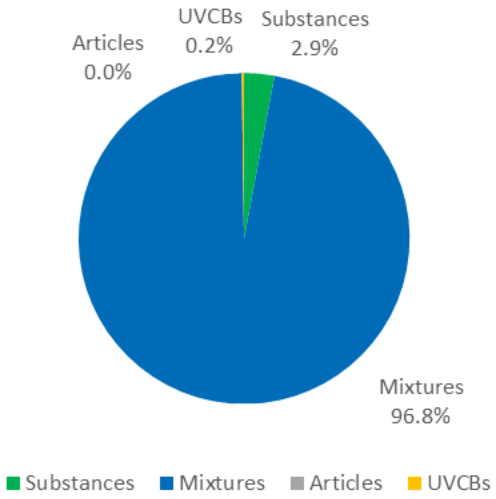


Figure 4-4, Figure 4-5 and Figure 4-6 present an overview of the sectors potentially most impacted by the changes to GRA by tonnage, turnover and number of products respectively, as indicated by the responses to the first consultation. It can be seen that the sectors, denoted by Product Category (PC) as defined in the ECHA R12 Guidance on information requirements and Chemical Safety Assessment[135], vary depending on the variable but the most significantly impacted sectors by tonnage band of products sold are:

- PC35: Washing and cleaning products;
- PC39: Cosmetics, personal care products;
- PC28: Perfumes, fragrances;
- PC3: Air care products;
- PC26: Paper and board treatment products;
- PC31: Polishes and wax blends;
- PC8: Biocidal products;
- PC29: Pharmaceuticals;
- PC14: Metal surface treatment products;
- PC51: Food contact materials; and
- PC1: Adhesives, sealants.

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.

[135] 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 4-4 Sectors most impacted by the addition of hazards to CLP and the extension of the GRA: Affected Sales Volume by Sub-sector (tonnage)

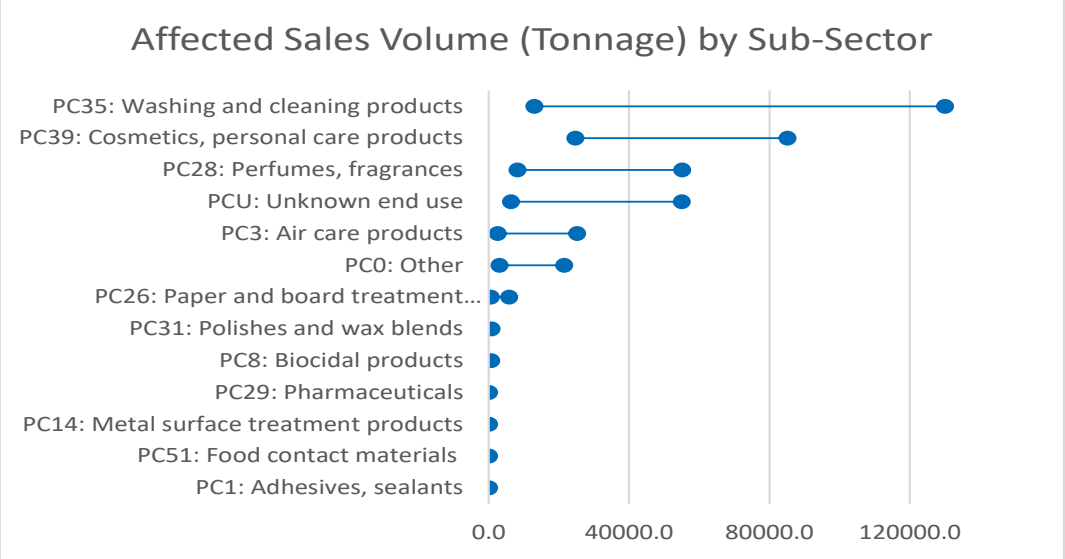


Figure 4-5 Sectors most impacted by the addition of hazards to CLP and the extension of the GRA: Affected Sales Volume by Sub-sector (turnover)

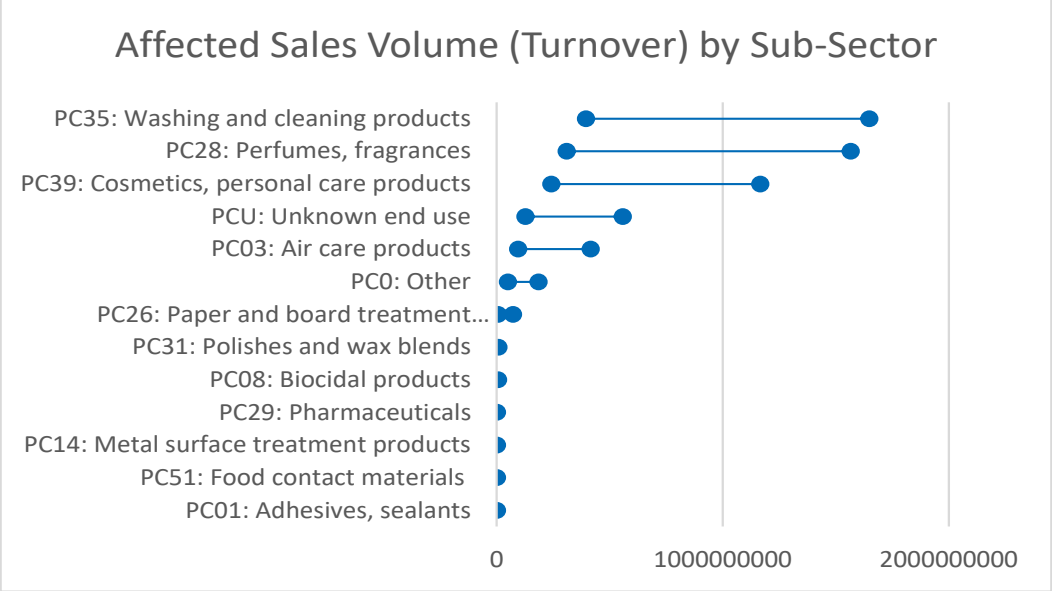
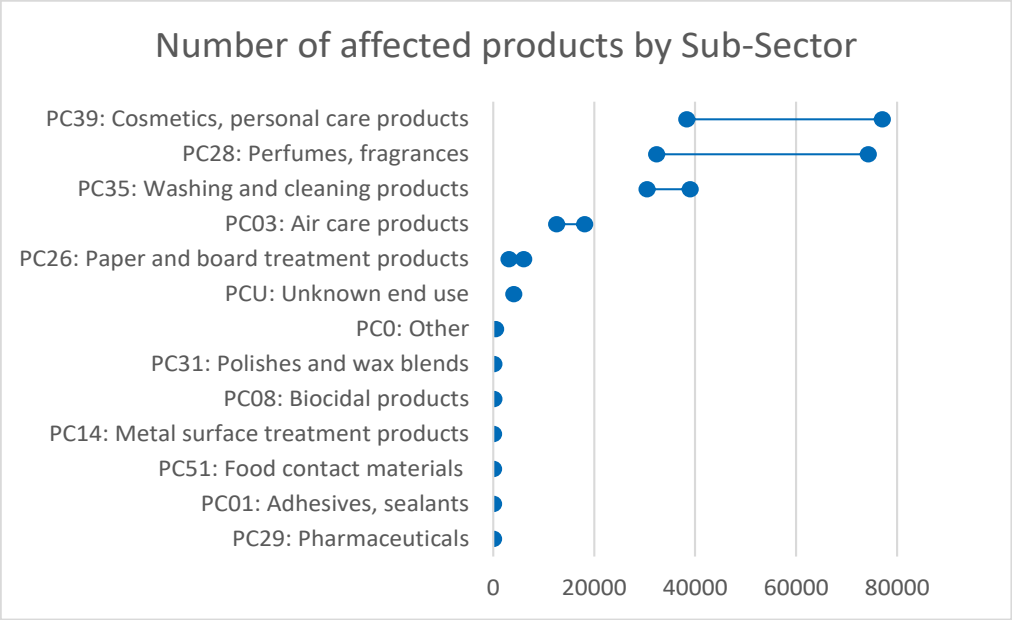


Figure 4-6 Sectors most impacted by the addition of hazards to CLP and the extension of the GRA: Affected Sales Volume by Sub-sector (number of products)



5 Business Impacts of the Policy Options

This section presents the ex-ante assessment of selected policy options already proposed within the CSS, with a focus on how the EU-27 fragrance 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 3.4, the most recent available data from Eurostat, evidence gathered through the survey of 30 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 fragrance sector, including impacts on sectoral turnover, production 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).

Finally, other business and economic impacts, especially on international trade and competitiveness, are considered more qualitatively drawing primarily on available literature evidence and the survey of participating companies (Section 5.2).

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 EU fragrance market and its competitiveness. For many companies within the sector, restrictions are to be placed on the use of substances in consumer and professional products (downstream user applications), meaning that the fragrance industry must seek to develop alternative substances in their complex mixtures or seek alternative substances for their formulations from their suppliers. As fragrances are complex mixtures, the ability to substitute or reformulate is limited by a number of factors, not least the ability to maintain the desired olfactory properties, but also to meet requirements for sustainability and certification.

Participating companies 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, members 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 30 respondents suggests that up to 27% of their portfolios in terms of turnover, which was equivalent to more than €2.2 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 fragrances that can only be mitigated through substitution and reformulation.

Once the 'affected portfolio' was established (27%), a follow-up business survey was implemented. Responses suggest that 33% of the portfolio of products that would be affected, directly by restrictions or bans or indirectly by pressures for market withdrawal, could be substituted and/or reformulated.

Businesses may, therefore, be able to mitigate or alleviate less than half of the potential restrictions that would be introduced with 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 faced by these businesses would lead to increases in CAPEX and OPEX per unit of turnover. These costs would be driven by new operating, capital and R&D

expenditures associated with substitution and/or reformulation; 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 fragrance 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 fragrance sector. Please note that the costs of the introduction of the essential use concept have not been quantified and as such, are not presented in the following sections.

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 fragrance 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) are intended to 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.

The List of Substances to be Regulated contained substances which had current classifications for the classifications of concern, and those which may be classified in the future, based on expert judgement of available data. Weightings have been applied to all potential future (F1 and F2) classifications to account for the fact that not all substances identified will be classified due to a lack of classification criteria for certain endpoints (ED, PMT, immunotoxic, neurotoxic), available data is not sufficient for classification or due to resource constraints. To note, the weighting accounts for the grouping of substances based on the ECHA Integrated Regulatory Strategy (2021). More detail can be found in Annex 5.4.

These reclassifications could also have indirect impacts, for example, companies may consider product discontinuation or substitution (e.g., as seen for CMR cat. 2 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 and downstream users, expectations from consumers and professionals, voluntary initiatives such as 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 extension of 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 (Article 68(2)) and sector specific legislation.

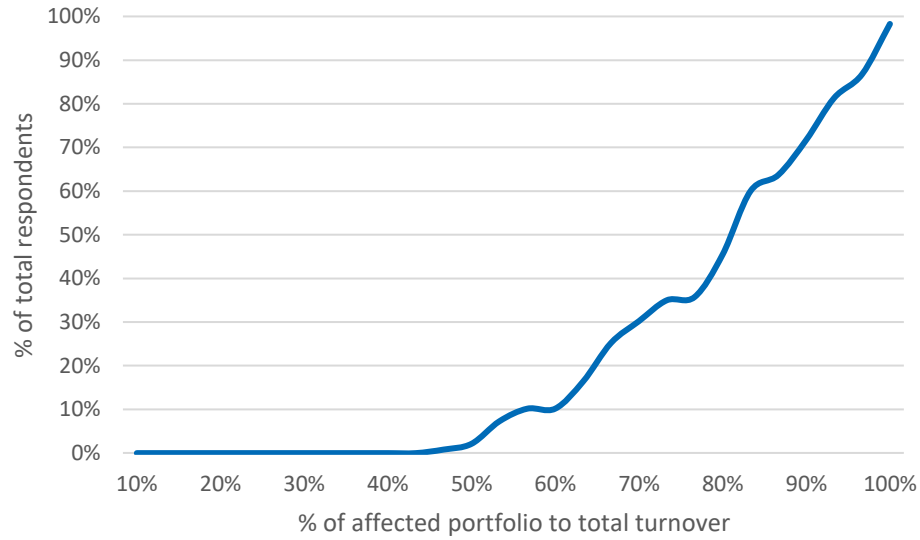
Table 5-1 Policy options considered for analysis in this study

Concrete Policy Option	Assumed regulatory action	Assumed entry into force
Addition of Hazards to CLP	New hazards classification: ○ Endocrine disruption (ED) ○ Persistent, mobile, toxic (PMT) ○ Very persistent, very mobile (vPvM)	2023
	Hazard classifications brought across from REACH: ○ Persistent, bioaccumulative, toxic (PBT) ○ Very persistent, very bioaccumulative (vPvB)	2023
	Hazard classification separated from established building blocks: ○ Immunotoxic ○ Neurotoxic	2032
Extension of GRA	Extend the generic risk approach to consumer and professional users via REACH Restriction, REACH Article 68(2) and relevant sector specific legislation: ○ ED ○ PBT/vPvB ○ PMT/vPvM	2024
	Extend the generic risk approach to consumer and professional users via REACH Restriction, REACH Article 68(2) and relevant 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 users via REACH Restriction, REACH Article 68(2) and relevant sector specific legislation: ○ Immunotoxic ○ Neurotoxic	2033
	Extend the generic risk approach to consumer and professional users via REACH Restriction, REACH Article 68(2) and relevant sector specific legislation: • CMR Cat. 2 • Skin sens. Cat. 1, 1A 7 1B • Aquatic chronic 1 and 2	2040

Over 30 businesses were asked to consider the products in their 2019 product portfolio that would be affected, if the policy options were to 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 27% of sectoral turnover, which would be equivalent to €2.2 billion in 2019.

There is a wide dispersion in the percentage of production that the affected portfolio represents. 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 24% and 9%, respectively, whilst the turnover-weighted average affected portfolio is 27%. Products that are already covered by the current GRA (and hence not a part of this study) are not considered for these calculations; only products affected by the extension of the GRA to new hazard classes proposed by the CSS are taken into account. This results in 43% of respondents having a potentially affected portfolio of size 0, as all their products were already covered. For the remaining respondents, their affected portfolios range between 1% and 98% of their turnover value, with a wide dispersion in results. Only a tenth of respondents present affected portfolios above 70% of their turnover value, while for 80% of them, it represents at most half of their turnover value. 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 fragrance 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[136] (F1/F2) are in place. It also captures all the restrictions defined as GRA for professional or consumer use products. This includes the restriction of skin sensitisers.

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

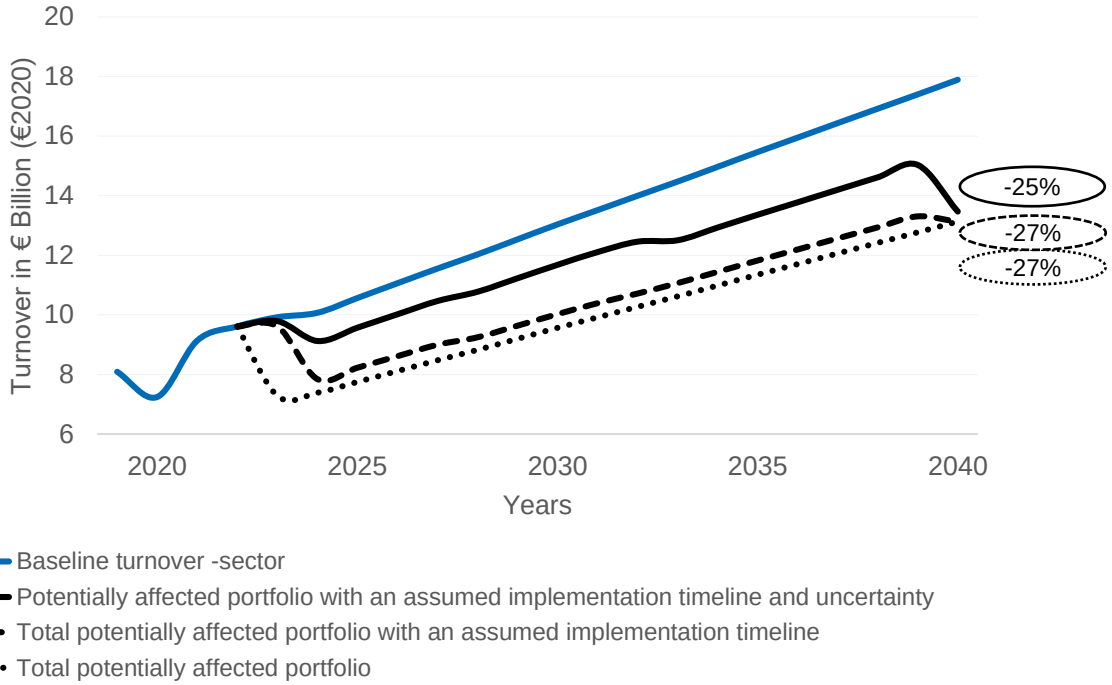
Therefore, the evidence collated was overlayed with a policy implementation timeline to produce the **'total potentially affected portfolio with an assumed implementation timeline'**. This timeline presents a phased approach for implementation, allowing for Commission impact assessments to be completed and new hazard classifications to be included in CLP. In essence, this step distributes the reductions in the EU fragrance sector's product portfolio from 2023-2040. 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 27% 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 Annex 5.4). 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 is expected to be lower and around 25% of expected sectoral turnover. This final version of the affected portfolio is expected to demonstrate the 'best estimate' given the available evidence from businesses and expert input with regards to the policy options considered in the study.

[136] CMR cat. 1A,1B,2; PMT; vPvM; PBT; vPvB; ED; STOT SE/RE cat. 1,2; Respiratory Sensitisers cat. 1, 1A, 1B; Immunotox; Neurotox; Skin Sensitisers 1, 1A, 1B; Aquatic chronic cat. 1, 2.

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 fragrance companies.

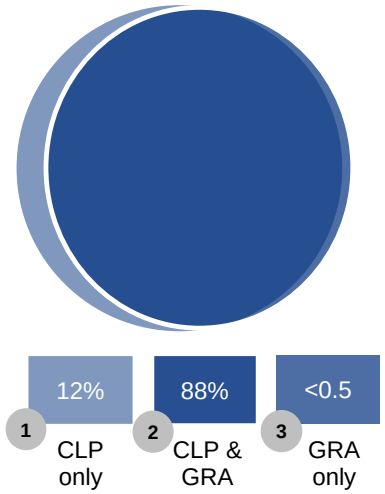
These estimates could be considered unlikely upper bounds for the potential reduction of the EU fragrance market in the event that the proposed changes to CLP and the GRA are adopted in full and the EU fragrance industry does not adapt, where possible, to mitigate these impacts. The final estimate of 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 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 fragrance 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 e.g. products with only an industrial end use will not be affected by the GRA. 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 (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 fragrance companies.

When changes to CLP and the GRA are implemented simultaneously, it is expected that 88% of the total affected portfolio of products will be facing substance manufacturing and/or use restrictions. The rest, 12% 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 IFRA suggests that, in response to the affected portfolio that may face direct restrictions/bans (88% of the total), businesses will substitute and/or reformulate around 33% of these products to mitigate the market losses. Box 5-1 outlines the evidence collected related to the EU fragrance sector's capacity to substitute and/or reformulate that has been considered in this analysis.

In addition, a quarter of the products that may only be affected by changes to CLP (equivalent to 3% of the total affected portfolio) are expected to face pressures, indirectly, 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

Around 30 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 by how their customers may react to the substitutes and/or reformulated products.

Further, over 20% of respondents suggest that substitution and/or reformulation could surpass 90% 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)[137] 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 33% of total potential market withdrawals resulting from regulatory changes and time taken 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 other three quarters of the products that may only be affected by changes to the CLP (equivalent to 5% of the total affected portfolio) will be subject to increased regulatory burden. In this case, the evidence collected suggests that businesses have some capacity to pass through some of this regulatory burden to their clients. Additionally, the survey responses suggest that overall sales of the EU fragrance sector are not very responsive to price changes (i.e., sales decrease less than proportionately to a given price increase). Therefore, the increase in regulatory burden is unlikely to affect the market significantly. However, in cases in which there might be strong or growing competition from players based outside of the EU, with different rules of play and lower regulatory burden, that situation could imply an opposite force on prices pushing them downwards.

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

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

Box 5-2 The EU fragrances 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, based on survey responses by 22 companies provided in 2021, from both large and SMEs, is estimated to be 19% on average – a simple average weighted by each respondent's turnover. However, that would not be expected to have a significant impact on prices, which was estimated to be lower than 0.5%.

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

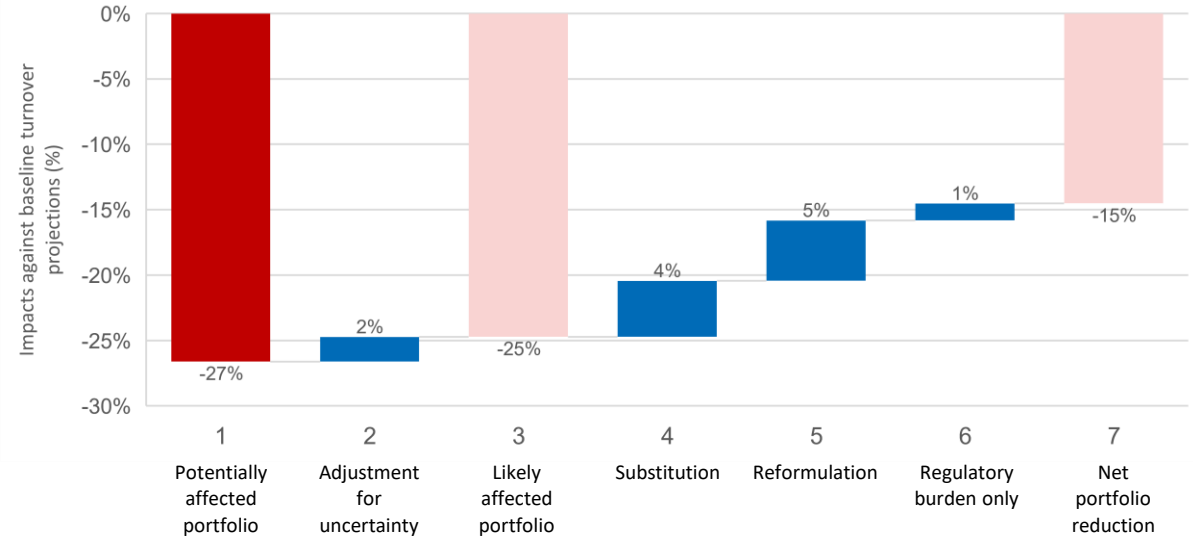
Overall, they considered that their products are, on average, price inelastic, with price elasticity of demand, based on survey responses, estimated at around -0.65. This means that the tonnes of fragrance products or quantity sold in the EU-27 are not very responsive to price changes, that is, a 10% increase in chemicals prices would only result in a 6.5% reduction in the quantity sold.

This means that, given the market dynamics of 2021 (when the consultation was undertaken), 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) if competition from international markets increases, or due to other unforeseen circumstances such as those within the global political landscape (e.g. political instability, humanitarian crises), which have not been considered in this study. Likewise, changes to the chemicals legislative framework in the future that exert greater competitive pressure on the rest of the market may have significant negative impacts on the ability of companies to pass on regulatory burden through price changes.

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

Finally, Figure 5-4 below illustrates the different stages 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 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 fragrance companies.

In brief, the total potentially affected product portfolio from potential changes to the GRA and CLP (**Stage 1**) can be adjusted by the weighting for F1/F2 classifications (**Stage 2**) to lead to the most likely affected portfolio, which is equivalent to 25% of the baseline turnover or market (**Stage 3**).

Around 4 percentage points of this market will likely be substituted (**Stage 4**), around 5 percentage points will likely be reformulated (**Stage 5**) and 1 percentage point of the market will not face pressures for market withdrawal and will only be affected by increased regulatory burden (**Stage 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 15% or equivalent to €1.2 billion in 2019 (**Stage 7**). The aforementioned business responses are, however, costly and will require an increase in both investment and innovation, and operating expenditure.

The following section delves into the net impacts of the policy options on the EU fragrance 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 fragrance businesses

The consultations with fragrance 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 fragrance 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[138] and long-term macroeconomic projections for the European economies from the OECD[139] . This baseline scenario assumes that CSS is not implemented, GRA is not extended, and CLP remains unchanged, except for periodical updates to Annex VI as a result of harmonised classification and labelling.
- A first policy scenario (**Scenario 1**) considers the addition of hazard classes to CLP and extension of the GRA over a gradual implementation timetable. 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 or reformulated. In addition, a quarter of products that are only affected by CLP (that is, not covered by the GRA extension) may 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 expected to be relatively small. Overall, in this scenario, the EU fragrance sector is estimated to lose €0.9 billion (€2020) of turnover each year[140] over the period 2023-2040, against the baseline scenario.
- A second scenario (**Scenario 2**) assumes a faster, 5-year implementation timetable of the expected changes to the GRA and CLP. This reflects the timeline indicated by the CSS Action Plan and the Restriction Roadmap intention for skin sensitisers. The faster implementation would require earlier and faster withdrawal of substances/ products from the market or their substitution and reformulation. It is assumed that businesses are able to respond and adjust operations immediately after policy adoption, with limited or unnoticeable delays. Over time, however, the size of the EU fragrance market is expected to converge to the Scenario 1 levels. Overall, in this scenario, the EU fragrance sector is estimated to lose €1.8 billion (€2020) of turnover each year[141] over the period 2023-2040, against the baseline scenario.
- 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

[138] Eurostat (2021), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 09/2021
[139] OECD (2018). *Economic Outlook No 103 – July 2018 – Long-term baseline projections*. [Online] Available from: Database.
[140] NB these are annualised turnover losses over the period.
[141] NB these are annualised turnover losses over the period.

and/or reformulated products to the market. Based on the available evidence[142], it has been assumed that companies may need, on average, around 4.8 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 expected in Scenario 2. Overall, in this scenario, the EU fragrance sector is estimated to lose €2.0 billion (€2020) of turnover each year[143] over the period 2023-2040, against the baseline scenario.

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 fragrance sector and the knock-on effects on the EU-27 economy were assessed against the baseline scenarios. These are described in nine sub-sections:

- Turnover
- Gross Value Added
- Intermediate consumption and operating costs
- Capital expenditure
- Research and Development
- Regulatory burden
- Employment
- SME versus large enterprises
- Professional, industrial and consumer use products

5.1.3.1 Turnover

The adoption of the policy options considered is likely and expected to lead to a reduction in size of the EU fragrance sector, either in terms of turnover and/or 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 business 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.

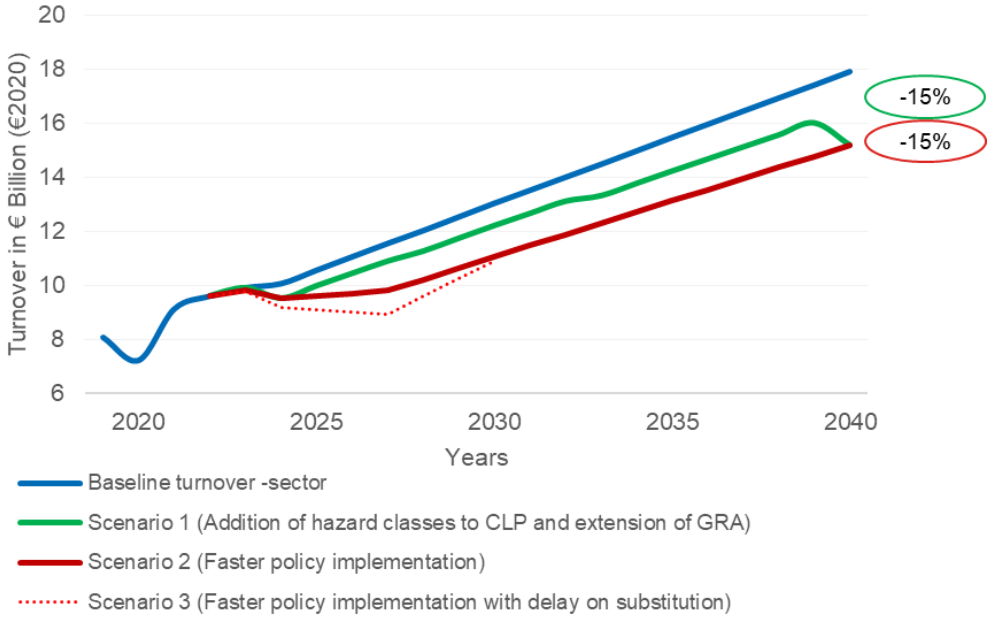
Table 5-2 Annualised impacts on the size of the EU fragrances sector against the baseline scenario in terms of turnover (€ 2020)

Scenario	First order effects or impacts on businesses overall
Scenario 1 (Addition of hazard classes to CLP and extension of the GRA)	The EU fragrance sector is estimated to **lose €0.9 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 fragrance sector is estimated to **lose €1.8 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 fragrance sector is estimated to **lose €2.0 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 5-5 below.

[142] 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
[143] NB these are annualised turnover losses over the period.

Figure 5-5 Estimated impacts on the turnover of the EU fragrances sector against the baseline scenario (€ 2020)



Source: Ricardo analysis based on Eurostat data and a bespoke survey to fragrance companies.
Note: The Y-axis has been truncated for ease 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 fragrance market would be around 15% lower than the expected 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 of fragrance companies. Overall, based on the data available, it is expected that companies would pass through on average around 19% of the additional regulatory burden resulting from the legislative changes and given that, as reported by survey participants, fragrance products appear to be price inelastic, this would mitigate the estimated reduction in turnover albeit marginally.

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 €0.9 billion to €2.0 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 fragrance sector already present the implications of key uncertainties around:

- the timetable for policy implementation (Scenario 1 vs Scenario 2 and 3)
- the time required for businesses to adjust their operations and place substitutes and/or reformulated products in the market (Scenario 2 vs Scenario 3)

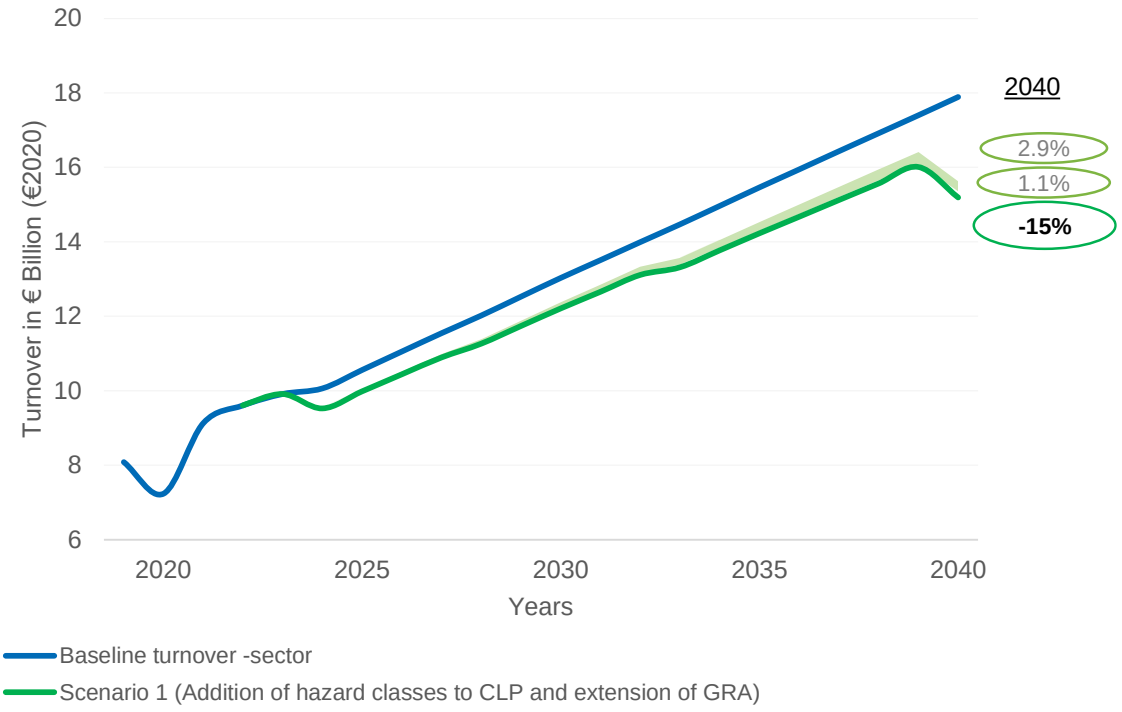
Within each of these scenarios there are other assumptions (see Section 4.2), and hence uncertainties, which could affect these estimations. In particular, the sensitivity of the results to the extent to which businesses may be able to substitute and/or reformulate has been explored.

As noted earlier in this section, if businesses do not substitute and/or reformulate at all, the EU fragrance sector could lose 25% of the turnover expected in the baseline (which is 67% larger loss than the central

[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 Commissions Better Regulation Guidelines.

estimate). The best available evidence, however, suggests that businesses will be able to substitute and/or reformulate 33% of their product portfolios (in terms of turnover). In any of these cases, turnover losses are not expected to vary significantly from the central estimate. This is illustrated in Figure 5-6 below. The central estimate for substitution and reformulation is the most conservative one and the most aligned with the clarifications provided by survey respondents. Different treatments of the reported data on substitution and reformulation make the impacted turnover estimate increase by 1.1% and 2.9%, but the levels of substitution and reformulation in the alternative treatments are larger and not in line with clarifications provided by 13 survey respondents in follow-up communications with the team (see Section 5.1.3.2).

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



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

Additionally, the substitute products in this scenario are not guaranteed to present the same characteristics and performance as the ones they are intended to substitute, so it is uncertain whether they are viable alternatives and would be accepted by consumers. Demand may have an impact on the price of alternative products. It should also be noted that the ability to substitute fragrance constituents does not necessarily allow for the product to be kept on the market. As many fragrance products are complex mixtures, substitution and reformulation are also complex, and certain products cannot be reformulated and so would be deemed an alternative product. These considerations may drive an impact beyond 15% of the sector turnover. For a more detailed overview, see Section 5.1.3.2 Notes on the expected business response.

Moreover, 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 fragrance 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 Section 5.1.3.3.

5.1.3.2 Notes on the expected business response

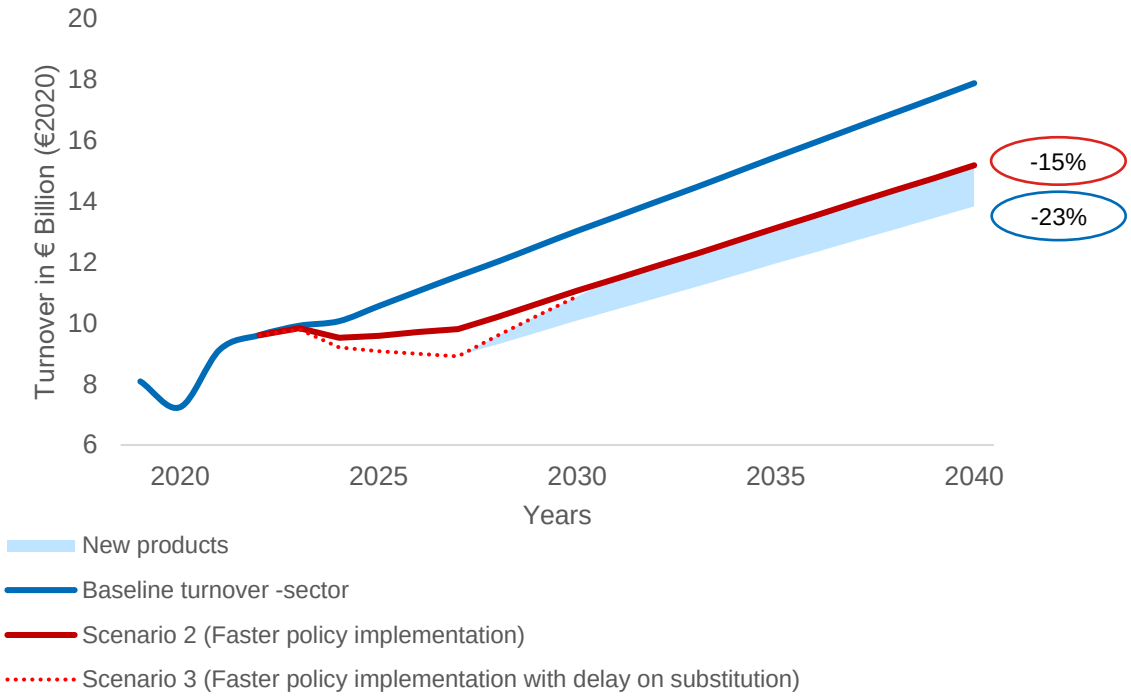
Follow-ups with participating companies have been conducted to understand the extent of substitution and reformulation. The numbers from the questionnaire on economic impacts of the GRA and CLP were complemented with additional information provided by 13 companies in the sample[145]. The main conclusions of all company reports, questionnaires and follow-up correspondence were as follows:

1. Companies expect to be able to avoid the loss of one third of the affected portfolio through substitution and reformulation of their products and/or their ingredients. A slightly higher share of this would be achieved through reformulation than with substitution, leading to the 5% reformulation and 4% substitution, as percentages over the whole fragrances market, that are shown in Figure 5-4 above.
2. While this may be the case, companies complemented these estimates with some qualitative aspects:
    a. The development of alternative substances is not applicable to companies that are just formulators, as they only produce and sell mixtures and/or products that depend on substance producers upstream. In the absence of new developments by their substance suppliers, this group can only reformulate, already with significant efforts in R&D, product testing, regulatory affairs and commercial efforts to deliver the new product to the public.
    b. Companies that do manufacture substances and that do have some readily available alternatives for substitution, claim that product performance and characteristics will not likely be paired with the products as they are today.
3. This last claim on product performance and characteristics was general among the companies that engaged with providing complementary information.

As a result of these, Figure 5-7 below illustrates this feature in the case of an accelerated implementation of the new hazard classes and subsequent extension of the GRA (i.e., Scenarios 2 and 3) with delays in substitution (Scenario 3).

[145] The 13 companies are a combination of large, and small and medium-sized companies covering more than 80% of the whole sample turnover.

Figure 5-7 Business turnover estimation in the baseline, policy scenarios 2-3, and illustration of the fraction of potentially new products



The area shaded in blue showcases the extent of products that are substitutes and/or new formulas of their baseline version. Products within that area may not match the products that were being produced and sold in the market before the regulatory changes come into force: they may have different characteristics, face different levels of competition from outside of the EU, both in terms of costs and performance, and ultimately, may not be sold at the same prices as their current versions or have the same demand. Consequently, the final turnover impact in such a scenario would be expected to be somewhere in between the red line, where all the new products are welcomed by the customers and able to be sold at similar prices as baseline products (15% turnover impact by 2040 with respect to a baseline projection), and the bottom-end of the blue-shaded area, where the newly developed products would find no market at all (23% turnover impact by 2040 with respect to a baseline projection).

Finally, this mismatch between the newly developed products and the baseline products is expected to be stronger in an accelerated scenario for policy implementation, while a more phased approach would allow companies more time to make the necessary investments on product development to mitigate this impact.

It should be noted that the criteria that must be met for new products has increased over time and now includes not only olfactory properties, but also regulatory and safety standards, sustainability and client pressures (removal of certain substances that result in certain classifications and subsequent pictograms, biodegradability etc).

5.1.3.3 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 fragrance 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 on 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 impacts or reduction in GVA.

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

Table 5-3 Estimated impacts on the GVA of the EU fragrances sector against the baseline scenario (€ 2020)

Scenario	Direct impacts on sectoral GVA
Scenario 1 (Addition of hazard classes to CLP and extension of the GRA)	The EU fragrance sector is estimated to **lose €0.3 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 fragrance sector is estimated to **lose €0.4 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 fragrance sector is estimated to **lose €0.5 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 €0.3 billion and €0.5 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 fragrance 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 fragrance 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 fragrance 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. These multipliers are based on evidence for the chemicals sector as a whole, in view of the lack of better granularity in the standard Input-Output tables.

Based on this, **total reductions in GVA driven by the effects of the policies considered on the EU fragrance sector could range between €0.8 billion and €1.7 billion every year on average between 2023 and 2040.**

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

5.1.3.4 Intermediate consumption and operating costs

43% of the fragrance companies surveyed for this study confirmed that they would be required to change their operations and manufacturing processes as a result of these policy changes.

First, the expected withdrawal of products from the market would necessarily imply that fragrance 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 €512 million.

Secondly, companies would also take action to find alternatives and/or substitutes to alleviate the expected reduction in their business. Thus, some of the current operations would need to be adjusted for the manufacturing and placing on the market of substitutes and/or reformulated products. Further, additional administrative and compliance requirements, such as adjusting the labelling of products, and associated costs would also be incurred. As an illustration, estimates based on the survey of fragrances companies suggest that an additional €296 million of recurring costs could be incurred as a result of substitution, reformulation, labelling and other CLP-related activities, by 2040 in all three scenarios.

Overall, intermediate consumption and operating costs are likely to fall. These net reductions on intermediate consumption and OPEX would be driven by the reduction in market size that is expected in the EU fragrance sector (see Section 5.1.3.1). 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 expected to increase. For example, the 'ratio of intermediate consumption to turnover' is likely to increase by up to 3% in 2040 against the baseline.

5.1.3.5 Capital and R&D expenditure

Similarly, the expected withdrawal of products from the market is expected to have some implications on the capital and R&D expenditure by fragrance companies. If the size of their business declines, it is expected that their overall expenditure will decline as well. As an illustration, a 10% reduction in the size of fragrance companies in the EU may lead to an eventual reduction in overall investment of similar proportion, which would be equivalent to reducing investment by around €24 million.

Nevertheless, these companies will also need to increase their investment and innovate as they work to, for example, change their manufacturing processes, identify quality substitutes and alternatives and reformulate their products. Based on the survey of fragrance companies, it is expected that an additional €456 million (€2020) would be invested over 10-15 years from the adoption of the policy changes to support these changes that fragrance companies would need to embark on to mitigate further operational and turnover losses.

Overall, net increases on intermediate CAPEX and R&D expenditure are expected, based on analysis from survey data. 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, but new large investments related to substitution and reformulation efforts would be incurred. Studies of the impact of REACH, such as CSES (2012)[146], highlight the likely negative effects from having to meet new compliance requirements and this leading to some reallocation of resources. In the absence of a realistic substitution and reformulation pathway, reductions in CAPEX and R&D would be observed of a similar size to the reduction in market size for the sector. This would be the likely situation in a scenario of accelerated implementation of the policies, while in a phased approach, sufficient time to actually develop new formulas and products would lead to net increases in CAPEX and R&D, compared to a baseline.

With net increases of CAPEX and R&D, unit expenditure would also increase, at least with regards to adjusting manufacturing processes and completing the required investments for effective substitution and reformulation. Based on the survey of fragrance companies for this study, the 'ratio of CAPEX to turnover' is expected to increase against the baseline by more than 50% on average, over the period 2023-2040 in a scenario with a phased policy implementation.

5.1.3.6 Regulatory Burden

Regulatory burden refers to all the administrative and compliance costs that result from EU legislation. This includes direct administrative costs (e.g., sharing information, engaging with administrative

[146] 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

processes 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).

Technopolis Group, VVA. (2016) estimated a regulatory burden affecting the EU chemicals sector of over 2% of turnover, which, for the fragrance sector in particular was estimated in 4% of turnover. This estimate was used to develop a baseline against which to assess potential impacts.

As a result of the adoption of changes to the GRA and CLP, **regulatory burden is likely to increase against the baseline from 4% to up to 7% of turnover, which is equivalent an additional €260-460 million in regulatory burden per year on average over the period 2023-2040.** This estimate includes both the additional CAPEX and recurring costs commented earlier in Sections 5.1.3.4 and 5.1.3.5. Please note that the regulatory burden related to the essential use concept has not been quantified and this may increase the overall regulatory burden on industry.

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 up to 28% of turnover by 2040, when compared to the baseline.

5.1.3.7 Employment

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

The scale of impact on employment is expected 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)[147], suggests that additional compliance costs 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, 3,000 jobs would be lost against the baseline scenario, which is equivalent to 11% of the fragrance sector's workforce. Table 5-4 below describes the estimated average impacts on the sector's employment in three scenarios.

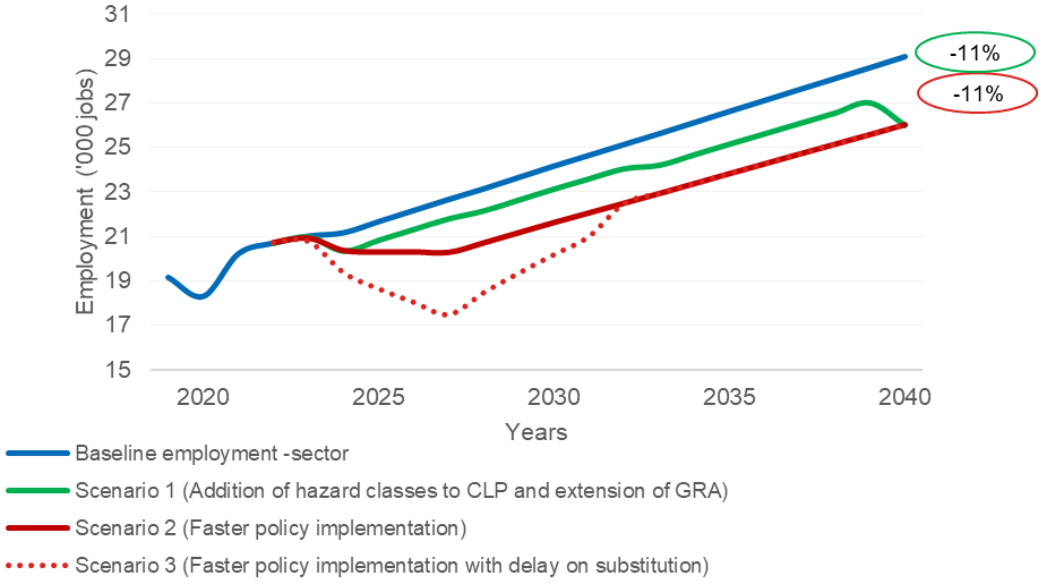
Table 5-4 Estimated average impacts on the employment of the EU fragrances sector against the baseline scenario (jobs)

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-27 fragrance sector is estimated to employ 1,200 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-27 fragrances sector is estimated to employ 2,300 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-27 fragrances sector is estimated to employ 3,600 fewer workers on average, when compared to the baseline scenario.

[147] CSES et al (2015). *Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs*. Available from: monitoring-the-impacts-of-reach.pdf

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

Figure 5-8 Estimated annual impacts on employment in the EU fragrances sector



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

As noted, the analysis suggests that the EU fragrance sector's employment would likely be 11% lower by 2040, equivalent to losing around 3,000 jobs in 2040 against a baseline. These effects are considered direct, in that they reflect the impact on the EU fragrance 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 fragrance 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 fragrance sector have been estimated using an Input-Output methodology. The cumulative Type I and Type II multipliers have been assumed at around 2.13 and 3.07 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 between 9,100 and 12,800 jobs by 2040 when compared against the baseline.

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

5.1.3.8 SME versus large enterprises

Whilst the evidence employed to assess impacts is deemed broadly representative of the EU fragrance industry, the sample disproportionally represents large firms in terms of turnover[148]. This might be an issue for estimating the average impacts on the whole sector, especially since only around 50% of the sectoral output is generated by large firms[149]. The group of large firms in the sector are accurately

[148] Surveyed large companies represent 89% of the sample turnover, while the overall sector distribution of turnover according to Eurostat data would be 48% for large firms and 52% for SMEs.
[149] Ibid footnote 113

represented by large firms that responded to the survey, but any outputs considered for small and medium sized companies will need to be treated as indicative or anecdotal only. Overall, 57% of the sector's turnover related to the production of fragrances, blends and raw materials is covered by companies responding to the survey.

The survey of fragrance companies suggests that the SME portfolio of fragrance products potentially affected by CLP and GRA could be smaller than the one identified for large companies (22% vs 27% of turnover). Of the affected portfolios, SMEs also report a higher expectation to find a substitute or new formula for their products (74% vs 32% of their potentially affected portfolio). 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, or a lower cost to have their products slightly modified, with potentially less flagship brands than larger companies. In this case, SMEs would expect fewer products withdrawn from the market (6% vs 17% for larger firms) and, therefore, a lower reduction in their turnover against the baseline than larger businesses, unless substitution becomes economically non-viable or international competition grows to the detriment of businesses in the EU.

Large business participants expected a relatively greater reduction in employment and a lower net increase in their capital expenditure, when compared to SMEs. In contrast, SME survey participants expected a relatively similar regulatory burden affecting their cost base, when compared to larger companies.

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 fragrance 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 suggests that SMEs may suffer disproportionately 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.

5.1.3.9 Professional, industrial and consumer use products

In the context of this study, some of the questions included in the survey allow us to draw some broad conclusions about the different types of products affected by the CLP and the GRA. 73% and 27% of the total fragrance turnover is reportedly attributed to the manufacturing of products for consumer and professional uses respectively, according to the survey to companies in the fragrance sector. Before the CSS actions were announced, 10% and 4% of the annual average expenditure on research and development was dedicated to discovering new alternative ingredients and formulas for consumer use and professional use products respectively, following a similar pattern to turnover by product type.

Finally, companies report that as a consequence of the addition of hazards to CLP and extension of the GRA, they expect 8% of their new regulatory costs to be driven by the extensions of restrictions to professional uses, suggesting that consumer use products might be the main driver of restrictions and costs invested in the development of new products.

5.2 Other business and economic impacts

This section explores other business and economic impacts, including how the policy options may affect the EU fragrance sector's competitiveness (section 5.2.1), its role in international trade (section 5.2.2) and illicit trade (section 5.2.3).

5.2.1 Competitiveness

The competitiveness of the EU fragrance 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[150]
- The skillset and the cost of the workforce[151]
- Operating/administrative costs[152]
- EU regulations, both for fragrance and other aspects such as emissions regulations[153]
- The effective enforcement of these regulations[154]
- Coordination and communication[155]
- The ease of access to markets[156]

A 2015 study by the 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[157]:

- 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[158,159]. That said, if regulation are not well designed, the administrative burden can weigh heavily on businesses, especially on SMEs.

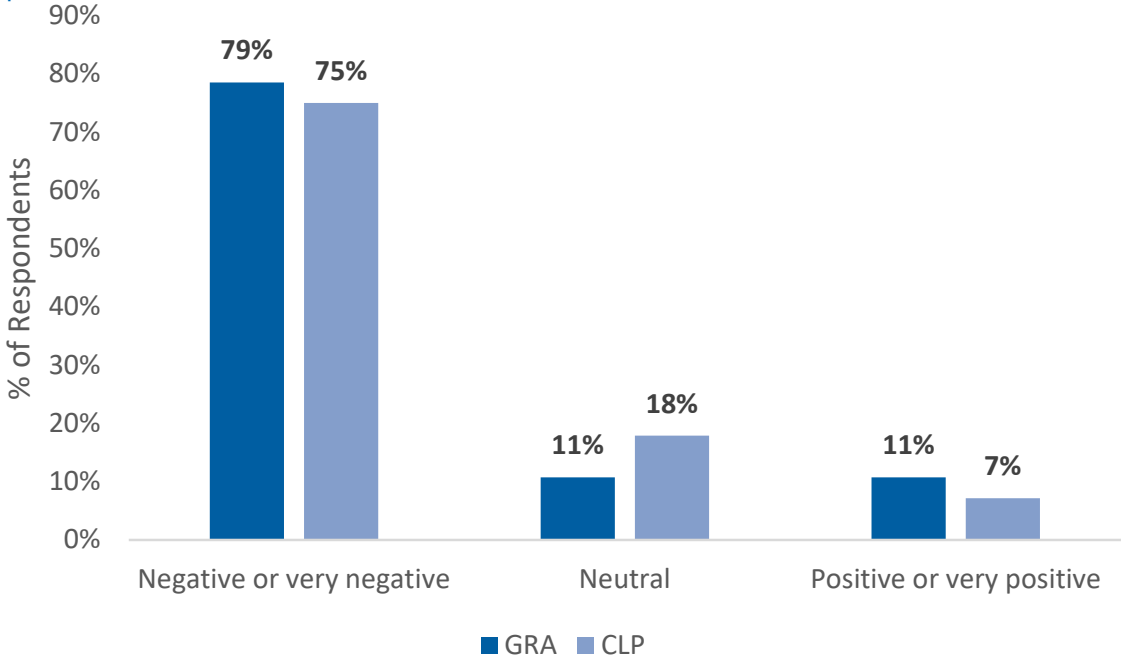
CSES et al. (2015) and Milieu et al. (2017) also agree that operational costs have the most prominent influence on competitiveness. Energy costs are a major influence on profit, with many companies stating the costs are likely to be at least partially absorbed by profit margins. This is confirmed by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

[150] Ibid footnote 56
[151] Ibid footnote 56
[152] Ibid footnote 32
[153] Ibid footnote 32
[154] Ibid footnote 56
[155] Ibid footnote 56
[156] 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)
[157] Ibid footnote
[158] Ibid footnote 56
[159] Ibid footnote 56

In OEC (2019)[160], competitiveness was assessed with respect to fragrance exports. From 2009 to 2019, the proportion of fragrance exports from the EU-27 decreased by 5 percentage points, from 29% to 24%. In parallel, emerging economies, especially India and China, have gained market share in the world exports of fragrances. Additionally, when regulation of imported products is not properly enforced, companies external to the EU have a competitive advantage.

Looking ahead to the implementation of the CSS, fragrance companies were surveyed and asked whether the proposed legislative changes to the chemicals sector are expected to affect their competitiveness. An average 77% of the survey participants responded negatively or very negatively; 14% of respondents did not expect any significant impacts on their competitiveness; and around 9% reported expecting a positive impact. Survey participants expect similar effects from changes of the GRA and CLP. This is illustrated in the Figure 5-9 below.

Figure 5-9 Business expectations about the impact of changes of the GRA and CLP on their competitiveness



A.I.S.E.[161] 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*"[162] allows the EU fragrance 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. However, there are other pieces of evidence that show how first movers may incur higher costs in the long run, so additional factors that will either create an especially large revenue advantage or prevent the company from falling victim to a cost disadvantage need to be evaluated whenever market entry plans are considered[163].

[160] OEC (2019) *Essential Oil Historical Trade Data,* [Online] Available at: https://oec.world/en/profile/hs92/essential-oils?yearSelector1=tradeYear1
[161] A.I.S.E. (2020). Comments on document CA/61/2020, CARACAL 37(17-18 – November 2020)
[162] Ibid footnote 56
[163] Harvard Business Review (2001) *First-Mover Disadvantage*, [Online] Available at: https://hbr.org/2001/10/first-mover-disadvantage

5.2.2 International trade

In the context of this study, exports refer to substances, mixtures and articles produced in the EU-27 but placed on the market outside the EU-27. In the baseline, exports of the EU fragrance industry are expected to grow. Nevertheless, the EU-27 fragrance industry is losing share in the world exports of fragrances, currently at around 24% of world exports. Other markets, especially India and China, will increase their share in the global trade of fragrances[164].

The majority of survey respondents (80 and 83%) 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 respectively. This would exacerbate the trends identified as baseline, and the EU fragrance sector would be 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 (see 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 (83%) expect the proposed legislative changes to reduce imports into the EU-27 arising from the proposed changes to legislation.

The survey did not require respondents to explain their expectations with regards to the impacts on Imports and Exports in and out of the EU. However, the addition of hazards to the CLP Regulation, leading to a divergence from the UN GHS, is expected to be a significant driver of impacts on trade in and out of the EU. By adding new classification categories the communication of hazards internationally will not be coherent. This will incur costs in the EU and externally and will encourage a decrease in international trade.

5.2.3 Illicit trade

Illicit trade is a widespread preoccupation among fragrance companies responding to the survey. The majority, or 59%, 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 from the changes to the GRA and CLP. Fragrances are commonly found in perfumes and cosmetics, these goods are in the top 10 industries that are targeted by counterfeiters, with goods making up more than 7% of global customs seizures in 2019[165]. The OECD – EUIPO 'Global Trade in Fakes' report highlights the top economies likely to be a source of counterfeit perfumery and cosmetics imported into the EU from 2017-2019 to be China, Venezuela and United Arab Emirates.

A consultation with the overall chemicals industry[166] highlighted some of the most common reasons expressed for his expectation:

- 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;

164 Ibid footnote 160
165 OECD-EUIPO (2021) *Global Trade in Fakes: A Worrying Threat*,[Online] Available from: 2021_EUIPO_OECD_Trate_Fakes_Study_FullR_en.pdf (europa.eu)
166 Johansen, B. et al (2021) *Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability* Report by Ricardo for the European Chemicals Industry Council (Cefic) [Online] Available from: https://cefic.org/app/uploads/2021/12/Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf

- An existing trend among consumers to seek out products that are better performing, despite the presence of hazardous substances.

6 Essential Use

6.1 Introduction

In the absence of a clear definition of essential use, this section provides a qualitative assessment of the potential impacts of an essential use derogation on the fragrance industry and presents key views of stakeholders in the ongoing debate.

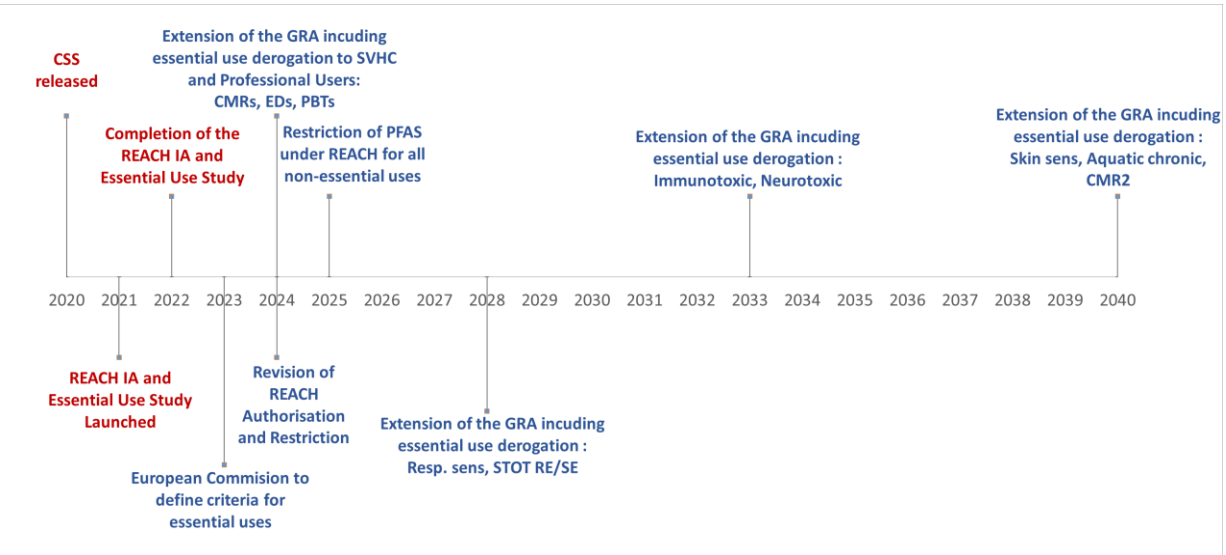
6.2 Context

The CSS has put forward a proposal to introduce a derogation from risk management based on essential use. The Commission has committed 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"*

The European Commission uses the term "essential" throughout the CSS and across multiple actions. From this we can directly link the concept with the restriction of endocrine disrupting chemicals, Per- or poly-fluorinated alkyl substances (PFAS), Substances of Concern and the extension of the Generic Risk Approach. Building from this the concept will be in conjunction with all expected extensions of the GRA across EU chemicals legislation, these have been displayed in the timeline below. In addition, the "essential use" concept is expected to feature as a justification for derogations from the GRA and authorisations under REACH. The existing REACH Restriction and Authorisation processes have been predicted to incorporate the essential use concept once revised, however more detail on the adoption of the essential use concept into REACH is expected after the impact assessment on the revision of the REACH Regulation is completed in 2022. A study on the development of the essential use concept is also expected to be published in the second half of 2022 which will provide guidance on the "essential use" definition to be confirmed by the end of 2022.[167]

Figure 6-1 Assumed Timeline of Implementation – Essential use.



[167] European Commission (2020) *Annex to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment*, COM (2020) 667 Final. Available from: EUR-Lex - 52020DC0667 - EN - EUR-Lex (europa.eu)

Information on the method of implementation, the definition criteria and the essential use decision process is currently scarce. However by analysing the information provided in the CSS on the Commission's intentions and comparing these with comparable enforcements of essential use currently in use, predictions can be made and impacts highlighted. The views of stakeholders have also been included to assess possible outcomes as these will undoubtedly influence the Commission's discussion on essential use.

6.2.1 Implementation

Currently the Commission is considering the inclusion of the essential use derogation in the Restriction proposal on PFAS.[168] This application of the "essential use" concept has gathered a lot of attention and consequently will influence how the concept is introduced across EU chemicals legislation. The risks posed by PFAS to human health and the environment have been investigated on multiple occasions, in particular fluoropolymer non-stick coatings have been a focus because of their ubiquitous use.[169,170,171] Using fluoropolymer non-stick coatings as an example: currently the resulting risk from this application is considered to be minimal and its use is permitted, but if all PFAS are Restricted unless the substance is proven "essential", the non-stick coating is expected to be banned. Currently the Restriction process requires a socio-economic assessment and the introduction of the "essential use" concept will require the process to operate differently. The current approach does not restrict the use of harmful substances which pose little direct risk, however the introduction of the precautionary approach will ban these substances unless they are deemed "essential". This focus on the hazard classification held by the substance and not the direct risk of the substance in use is expected to increase the number of Restrictions across all sectors. The expected increase in Restrictions has led many to consider their mitigation options, including reformulation, substitution or applying for a derogation. This prediction of an increase in Restrictions in combination with the lack of clarity on the essential use definition has made the concept a focus of conversation amongst all key stakeholder groups.

When discussing the proposed PFAS Restriction The American Chemistry Council opposed the application of the essential use concept, stating the use cannot be justified to restrict a whole group of substances as the concept is not robust.[172] Cefic has also conveyed concerns regarding the novelty of the concept in international and European law.[173] Industry, trade bodies, Member States and NGOs have all raised concerns on the implementation of "essential use" across multiple pieces of legislation. Cefic described the application of the concept as likely to cause a radical change to the current system.[174]

By including the concept of essential use under the extension of the GRA to all consumer and professional-use products, multiple pieces of EU chemicals legislation will need to be adapted. The CSS Action Plan specifically mentions the extension affecting the REACH Regulation, the Food Contact Materials Regulation, the Cosmetic Products Regulation and the Toy Safety Directive but many more are expected to also include the "essential use" concept. The revision of REACH will have the broadest impact across the EU chemicals industry, including the fragrance sector. The current requirements of the Restriction process include, but are not limited to, an evaluation of the risk associated with a particular use, an assessment of the requirement for this use including societal impacts, and the possible use of alternatives. Specifically, Article 68 of REACH covers the need to evaluate alternative substances as well as the possible socio-economic impact of the Restriction. This Article has been

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[168] 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
[169]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
[170] Bundesinstitut für Risikobewertung, (2019). Neue gesundheitsbezogene Richtwerte für die Industriechemikalien PFOS und PFOA. DOI 10.17590/20190821-105231
[171] 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
[172] 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
[173] 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
[174] Ibid footnote 173

described as comparable to the "essential use" concept.[175] ClientEarth supports this comparison and argues the REACH requirements on Restrictions, including the socio-economic analysis in Annex XVI, are in tune with the concept of "essential use". The NGO described the Annex as allowing for ample discretion on the scope and level of detail of the socio-economic analysis required. This has led ClientEarth to suggest the concept could be introduced without delay and should be included in the current Restriction proposal on PFAS.[176] Although this imminent introduction is not supported by the law firm Jones Day who states that a legislative act will be needed to incorporate essentiality. The law firm stresses the need for an amendment to Annex XVI as a minimum, or the addition of a legislative act to Article 60(4), under the conditions for Authorisation, and the addition of Restriction derogations in Article 68(1) for a more comprehensive approach.[177] A recent article on "*The Concept of Essential Use*" agrees with Jones Day on this topic, stating the use of terminology similar to The Montreal Protocol on Substances that Deplete the Ozone Layer (the Montreal Protocol) definition of "*necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects)"* will definitively separate the concept from the current socio-economic approach in Annex XVI.[178]

From the information provided in the CSS on the essential use definition and the indicative timing of the GRA and revision of REACH, it can be determined that amendments to REACH are expected and the application will not be instantaneous. The concept of essentiality is far broader than the current socio-economic analysis and thus amendments will be necessary. The amendments to REACH and the extension of the GRA will alter the general risk management approach of most EU chemicals legislation to one based on the precautionary principle and the concept of essentiality. A recent publication on the European Commission's Chemicals Strategy for Sustainability highlighted the introduction of essential use as a "*significant departure from the current system for REACH Restrictions*".*[179]* The change of approach will incur increased regulatory costs across industry due to the need to adapt, this regulatory burden has not been quantified in this report as this assessment of the impacts of the essential use concept is qualitative. However it is expected that companies will need to invest in educating and possibly broadening their regulatory department alongside assessing their product portfolio to determine the possible loss of products, opportunities to substitute or reformulate and consider the validity of applying for an essential use exemption.

The essential use concept will be applied across EU chemicals legislation including sector specific legislation, which has led stakeholders to raise concerns on the topic of coherence. SMEunited has expressed particular concerns regarding the coherence of approach across the legislative framework, emphasising the risk of conflicts with other legislation.[180] Concerns on compatibility have also been expressed with regards to EU treaties and, external to the EU, with World Trade Organisation (WTO) requirements.[181] Arguments have also been made on the possible hinderance to compliance the concept may incur. Although one of the aims of the CSS is to simplify and streamline chemicals legislation to increase compliance, some argue this concept will cause the opposite. A recent article on the concept of essential use, states the concept holds the potential to accelerate Authorisations and exemptions once the criteria to determine what is "non-essential" is defined.[182] This is assuming a clear definition of "essential" which then could be easily applied without the need for excessive discussion. SMEunited does not agree with this sentiment, they believe the decision-making process will be increased leading to delays in the Authorisation and Restriction process. They linked this to a decrease in compliance, as well as highlighting the risk of "more intense and political" advocacy efforts on certain substances or uses. An article questioning if the CSS is "all rooted in sound scientific evidence" also

[175] 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
[176] 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
[177] 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.
[178] McLaren, L., Moore, R. , & Majer, A. The European Commission's Chemicals Strategy for Sustainability: The Challenge of Matching Political Aspirations with Workable Regulatory Outcomes, International Chemical Regulatory and Law Review, Volume 4, Issue 1 (2021), pp. 3 - 8
[179] Ibid
[180] SMEunited (2020) *Comment to the REACH-AP 4.3 (Essential uses).* Available from: Copy of Copy of 17 - SMEunited_comments_CA_61_2020_Essential uses (REACH AP 4.3)_Redacted.pdf
[181] 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
[182] Montfort, J. *The Concept of Essential Use to Regulate Chemicals: Legal Considerations*, International Chemical Regulatory and Law Review, Volume 4, Issue 1 (2021), pp. 9 – 20.

stresses the expected increased workload expected as a consequence of the "essential use" concept.[183] In addition, a Position Paper on "*Essential Use Concept its Scope of Application*" written by an alliance of 32 Industry Associations predicts the assessments to require a "*strenuous*" level of detail.[184] The consequential burden of work for the applicant and for the assessing committee will be determined by the level of complexity and clarity in the essential use criteria. The majority of the proof will be provided by the applicant, as with The Montreal Protocol, and it is expected for the applicant to prove essentiality. From here the assessing committee will make a decision. The specific criteria of the definition will dictate the volume of supporting information required and the detail of the assessment to follow. Depending on the Commission's approach to the criteria for definition there is the possibility for this procedure to be lengthy and complex with the majority of the burden resting on the applicant.

6.2.1.1 Definition

The CSS states chemicals are essential if "*their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health"*. The commission also references the Montreal Protocol in the strategy and in the Action Plan, other than this, the CSS does not elaborate on the definition of "essential".

In order to protect humans and the environment "*while still allowing for the use of these most harmful chemicals where proven essential for society*" the Commission must first define what is "essential" in detail. This term is not frequently used in EU chemical legislation but does occur in global chemicals legislation. The first use of this concept can be found in the 1978 amendment to the Toxic Substances Control Act (TSCA) in the United States. "Non-essential" aerosol sprays were banned under the Act, this amendment was quickly mimicked by Canada, Sweden, Norway, Denmark, and Finland.[185] Then in 1992, at the Fourth Meeting of the Parties, an amendment was made to the Montreal Protocol on substances that Deplete the Ozone Layer to include an exemption for "essential uses".[186] To this day the Montreal Protocol is the most prominent implementation of the essential use concept across chemicals legislation. The Chemicals Strategy for Sustainability specifically references the essential uses definition below present in the Montreal Protocol on substances that Deplete the Ozone Layer in the CSS.[187]

> "*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."*

The term "essential use" is not currently defined within EU law but will need to be before the concept can be implemented into chemicals legislation. The definition above has been referenced as a base from which the new definition could develop, however the Montreal Protocol has a very narrow focus when compared to legislation such as REACH. The Protocol was designed to address specific, and

[183] Herzler, M., Marx-Stoelting, P., Pirow, R. *et al.* The "EU chemicals strategy for sustainability" questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence?. *Arch Toxicol* 95**,** 2589–2601 (2021). https://doi.org/10.1007/s00204-021-03091-3
[184] An alliance (2021) *ESSENTIAL USE CONCEPT, Position Paper on its Scope of Application*.
[185] 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.
[186] UNEP, 1992, Decision IV/25, '*Essential Uses*', *4th Meeting of the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer*. Available at: Decision IV/25: Essential uses | Ozone Secretariat (unep.org)
[187] 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

known environmental pollutants (Chlorofluorocarbons and hydrochlorofluorocarbons), therefore the essential use definition implemented here is only applicable to a select group of chemicals and applications. It would be expected for the definition to require adjustments if applied across the EU chemical industry to multiple sectors.

Under the 2001 Stockholm Convention on Persistent Organic Pollutants it is possible to seek a derogation for an "acceptable purpose".[188] This operates in a similar way to the expected extension of the GRA in combination with the essential use concept, the Convention takes a precautionary approach but allows parties to register for acceptable use.[189] Although this term has not specifically been used in EU chemicals acquis, Article 55 of Regulation (EU) No. 528/2012 on Biocidal Products lists a number of derogations including if the "*active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available*" again this echoes a similar message to the concept of essential use described in the CSS.[190,191] Similar to the Montreal Protocol, these derogations or exceptions are currently only applied to a specific sector or group of substances[192], the essential use concept will be applied across all EU Chemicals legislation and thus will need a more thorough implementation and explanation.

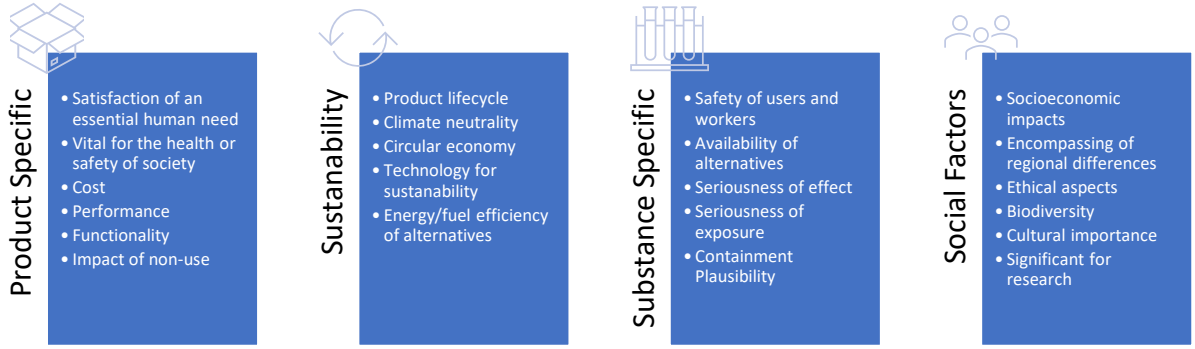
The CSS describes the GRA as "*simpler, generally faster and provides clear signals to all actors*" these are all factors which will also be important in the defining of the essential use criteria. To ensure a simple and clear application of the essential use concept it has been suggested by the Commission to predefine the essential use criteria.[193] This suggestion was welcomed by NGOs such as ClientEarth who believe a predefined list of criteria as well as a list of non-essential and essential use categories would increase the efficiency of the decision-making process. In addition, ClientEarth suggested only certain sectors may apply for essentiality if not on the predefined list thus reducing the number of possible applicants.[194] Trade bodies, including Cefic, do not agree with this suggestion and have argued a restriction based on non- essential use should only be implemented after a case-by-case assessment.[195] Cefic are not alone in suggesting a case-by-case approach, the DUCC as well as some industry respondents to a European Commission document have also expressed their support for a more tailored implementation.[196,197,198] If the Commission were to predefine uses deemed to be essential and the criteria of essentiality this could provide clarity and a clear signal to stakeholders. This in turn would lower the number of declined applications for derogations, and therefore the investment in unnecessary regulatory costs, and provide guidance for innovation. However a predefined list of uses would need to be constructed with in-depth cross industry knowledge and be subject to regular revisions. The list may prove to be restrictive or overly lenient as the selection of predefined essential uses would not receive the same level of accuracy as a case-by-case assessment. However the use of case-by-case assessments for every essential use application would create a large burden for the responsible committee and lead to large delays in the regulatory process.

The Action Plan in the Annex to the CSS sets out the indicative timing for the definition of the "*criteria for essential uses, taking into account the definition of the Montreal Protocol*" to be from 2021 to 2022. With the definition pending many have weighed in on what the criteria should include. The EU Council of Ministers considers the Montreal Protocol to be a "*good starting point*" but stresses the need for

[188] Stockholm (Sweden), (2004) *Overview* [Online] Available at: Overview (pops.int)
[189] Ibid
[190] Montfort, J. *The Concept of Essential Use to Regulate Chemicals: Legal Considerations*, International Chemical Regulatory and Law Review, Volume 4, Issue 1 (2021), pp. 9 – 20.
[191] Ibid footnote 173
[192] The Stockholm convention applies to persistent organic pollutants which are organic chemical substances with specific properties that pose a threat to the environment. Regulation (EU) No. 528/2012 only applies to Biocidal products.
193 Luke Buxton, (2021) Essential use: EU trade bodies say case-by-case approach should be the rule, [Online] Chemical Watch. Available from: Essential use: EU trade bodies say case-by-case approach should be the rule (chemicalwatch.com)
[194] 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
[195] Ibid footnote **Error! Bookmark not defined.**2
[196] 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
[197] Cefic (2020) *Regulating Chemicals Based On The Essential Use Concept*. Available from: Regulating chemicals based on the essential use concept - cefic.org
[198] 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

adaptations to account for the broader scope of this concept.[199] As well as the need for the definition to be applicable to the breadth of the sector, many industry stakeholders have also expressed concerns on the subjective nature of possible "essential use" definitions. It has been suggested the ideal definition may vary according to the age, cultural background and or region of the respective deciding individual.[200] The American Chemistry Council similarly provided an approach that would accommodate many influences, including cost; performance; product lifecycle and safety. The Council concluded from this approach a comprehensive definition could be put in place. AmCham list multiple possible criteria to be assessed such as socioeconomic impacts, functionality, regional differences and the availability of alternatives.[201] However, referring back to previous concerns on delays to the decision-making process, the benefits of multiple "essential use" criteria will need to be evaluated, taking into account the level of added complexity and the possible delays to the regulatory process. Figure 6-2 provides a summary of suggested considerations for the essential use criteria.

Figure 6-2 Summary of suggested aspects of importance to be included in the essential use criteria in response to the European Commission's discussion paper on essential use[202]



6.2.2 The Breadth of Applicability of the Concept

It is expected for the essential use definition to include *"cultural and intellectual aspects"* as both the Montreal Protocol and the Biocidal Products Regulation make reference to these aspects of essentiality. This part of the concept will be particularly subjective, many have speculated on the breadth and depth of this factor of essentiality. As mentioned previously, the Montreal Protocol is applicable only to a small number of chemicals which are known to be damaging to the environment, however as the most prominent use of this exemption it does provide a useful example of the possible outcomes. Under the Montreal Protocol only a small number of "essential use" exemptions have been granted and these have been within the following sectors: fire protection, crop protection, medical uses, laboratory and analytical uses, process agents and aerospace applications.[203] It can be noted that no "essential use" exemptions have been granted for consumer goods, however, this can be linked back to the scope of the Montreal Protocol.

It has been argued that cosmetic products, toys and other consumer goods are required for certain societal needs but may be viewed as not "essential".[204] Whether these uses and their influence on society will be included under the concept will rest on the details of the definition. Consumer products may meet the requirements for essentiality under the "*critical for the functioning—of society*"-*"encompassing cultural and intellectual aspects*" depending on the final phrasing of the definition. With the Commission's aim to provide clear signals to all actors by extending the use of the GRA it would be pertinent to continue this clarity into the essential use derogation and ensure a detailed set of criteria. Any ambiguity with respect to the applicability of the concept may lead to an extensive loss of time and

[199] 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
[200] Ibid footnote 196
[201] Ibid footnote 182
[202] Responses to the European Commission's question 8. "Do you have initial ideas on criteria or definitions that might help to decide whether a use might or not be essential?" Comments from REACH FR competent authority, ClientEarth Fluoropolymers Product Group and Cefic. Supported by additional information from Ibid footnote 168
[203] Ibid footnote 186
[204] Ibid footnote 181

an increase in regulatory costs for manufacturers hoping to receive an essential use derogation. This lack of clarity is also expected to have a negative effect on innovation in the sector, with funds being relocated to regulatory applications instead of research and development. Whereas a clear set of criteria could be expected to boost innovation and provide confidence to industry to support their internal innovation strategy. It is understood amongst all stakeholders that an increase in regulatory predictability supports the sectors growth and competitiveness.

Many fragrances have historical significance and are ingrained in cultural traditions. The importance of fragrance and their associated traditions was highlighted in 2018 when UNESCO recognised the olfactory heritage of perfume making in the region of Pays de Grasse in France and these skills were added to the list of the Intangible Cultural Heritage of Humanity.[205] Although the cultural importance of certain fragrances has been widely accepted, the ability to prove a substance's essentiality through cultural importance may not be simple. Alternatively the essentiality of the substance may need to be proven in conjunction with the value added via their use. In reply to the European Commission's discussion paper on essential use, multiple stakeholders stated the use of consumer goods as non-essential.[206] However external to responses to this discussion paper, some industry stakeholders argue fragrances are vital to encourage good hygiene, as they mask the unpleasant smell of the cleaning product and increase product use which has been particularly pertinent during the pandemic.[207][208] The value added by the inclusion of a fragrance in the cleaning product formulation from a marketing perspective is well known[209] but it will be necessary for industry prove the essentiality of a fragrance (if banned under the GRA or restricted under REACH) for this role, as well as proving there are no viable alternative fragrances which impart the same practices of good hygiene.

The use of fragrances is not restricted to consumer goods, it has been shown that some fragrances have the ability to affect an individual's wellbeing through their mood. Studies have shown certain fragrances can reduce the marker for anxiety, whereby certain scents have anxiolytic effects which have been compared to the outcomes of pharmacological treatments.[210][211] This "*olfactory modulation of mood*" has also been suggested as a treatment for multiple mood disorders such as depression, insomnia and the emotional disturbance which occurs alongside dementia. Studies have reported positive results after aromatherapy treatment for Alzheimer's disease, dementia generally and geriatric syndrome. The results reported improvement in orientation and balance as well as a reduction in irritability- related agitation.[212,213,214] Other studies have highlighted the benefits of "light-smell stimulus" in lowering blood pressure and altering mood in a manner suitable for treating depression, anxiety and stress.[215,216] These applications of fragrance may prove pertinent if such substances were to fall under the extension of the GRA. Research on olfactory based treatments is still ongoing and innovation in this area will be significant to the fragrance industry. Research into the medical use of fragrances may influence the impact felt by the sector after the expected extensions of the GRA, specifically the extension to include skin sensitisers.

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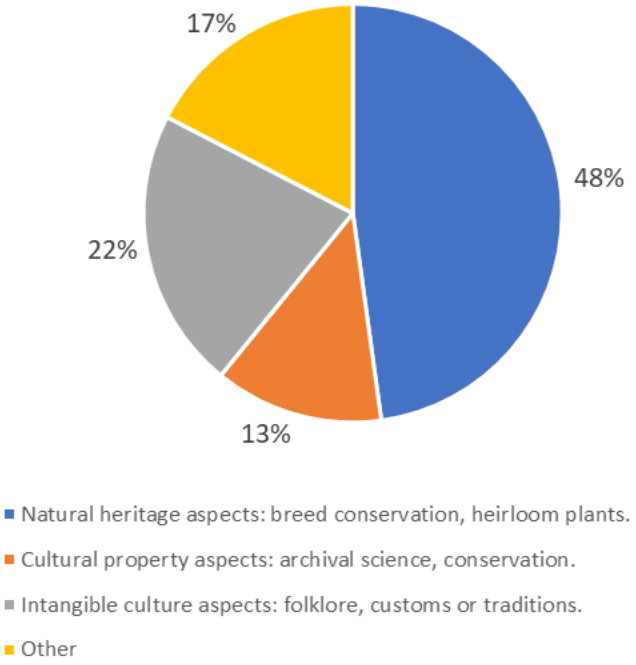
[205] United Nations Educational, Scientific and cultural Organization (2018) "*Convention For The Safeguarding Of The Intangible Cultural Heritage, Thirteenth session"* Available from: https://ich.unesco.org/en/13com
[206] Ibid footnote 194, and REACH FR competent authority,(2021) QUESTIONS TO CARACAL - *preliminary thoughts.* And BEUC, (2020) *Essential Uses – A possible concept for REACH.*
[207] Megan Marfilius, 2016, The Smell of Clean: Fragrance Drives Consumer Preference in Cleaning Products, Perfumer & Flavourist, [Online] Available from: https://www.perfumerflavorist.com/fragrance/trends/news/21879820/the-smell-of-clean-fragrance-drives-consumer-preference-in-cleaning-products
[208] ChemicalSafetyFacts, nd, Fragrances, Available from: Fragrances - ChemicalSafetyFacts.org
[209] Strugnell, C. and Jones, L. (1999), "Consumer perceptions and opinions of fragrances in household products", Nutrition & Food Science, Vol. 99 No. 4. https://doi.org/10.1108/nfs.1999.01799daf.002
[210] Warden-Smith, Jeremy, Paul, Laboni, Olukogbon, Kasope, Bointon, Emma S, Cole, Richard H, John, Sarah R, Dong, Shan and Jacob, Tim J C. "Light and smell stimulus protocol reduced negative frontal EEG asymmetry and improved mood" Open Life Sciences, vol. 12, no. 1, 2017, pp. 51-61. https://doi.org/10.1515/biol-2017-0006
[211] Kontaris I, East BS, Wilson DA. *Behavioral and Neurobiological Convergence of Odor, Mood and Emotion: A Review.* Front Behav Neurosci. 2020 Mar 10;14:35. doi: 10.3389/fnbeh.2020.00035
[212] Ebihara, T, Yamasaki, M, Kozaki, K, Ebihara, S. *Medical aromatherapy in geriatric syndrome*. Geriatr. Gerontol. Int. 2021; 21: 377– 385. https://doi.org/10.1111/ggi.14157
[213] JIMBO, D., KIMURA, Y., TANIGUCHI, M., INOUE, M. and URAKAMI, K. (2009), *Effect of aromatherapy on patients with Alzheimer's disease*. Psychogeriatrics, 9: 173-179. https://doi.org/10.1111/j.1479-8301.2009.00299.x
[214] Watson K, Hatcher D, Good A. *A randomised controlled trial of Lavender (Lavandula Angustifolia) and Lemon Balm (Melissa Officinalis) essential oils for the treatment of agitated behaviour in older people with and without dementia*. Complement Ther Med. 2019. doi: 10.1016/j.ctim.2018.12.016.
[215] Dong S, Jacob TJ. *Combined non-adaptive light and smell stimuli lowered blood pressure, reduced heart rate and reduced negative affect*. Physiol Behav. 2016, doi: 10.1016/j.physbeh.2016.01.013.
[216] Jacob, Tim & Warden-Smith, Jerry & Kernot, Neil & Galay Burgos, Malyka. (2017). *Using Frontal Brain Asymmetry to Control Sensory Treatment of Anxiety and Depression*. 84-88. 10.5220/0006471000840088.

When asked about whether they would expect the extension of the GRA or the new hazards to CLP to have an impact on the preservation of the cultural heritage of the EU-27 in the 10 years after adoption, 77% of survey respondents to our economic consultations responded they indeed would. Specific aspects of cultural heritage that the surveyed businesses expect to be impacted by the extension of the GRA and CLP are presented in the graph below.

Figure 6-3 Aspects of the cultural heritage that respondents expect to be impacted by the extension of the GRA and CLP (n=23).



Many decisions will need to be made over the next year to form a clear definition of essential use. The European Commission has started their discussion on the definition, but many have raised concerns about the parties present in these discussions. Opinions vary on who is best to decide what is essential, SMEUnited, for example, believes these factors of essentiality should be determined by society.[217] Whereas, ChemSec has commented that scientists and companies that profit from chemicals are not positioned correctly to decide on the definition. They argue the concept must "be decoupled from all kinds of economic considerations".[218] It can be argued that a diverse group of participating stakeholders will produce a robust definition. Keeping in mind the need for applicability across the chemical industry, the definition will need to be inclusive of all sectors. As well as broad applicability the definition also needs to be clear to all stakeholders across the EU and across the various chemical sectors. The phrasing and terminology used in the essential use definition may prove particularly divisive because of the concept's subjective nature, direct translations of the definition may not be possible in all EU languages, reinforcing the issue of clarity. Therefore, a lack of awareness or diversity in the discussions could lead to an uncomprehensive set of criteria or ambiguity based on the phrasing.

Once a definition has been written into EU Law a committee will be selected or created to decide on essentiality based on the definition. The Commission has not disclosed their decision on this committee, this is expected to factor into the current study supporting the development of the concept of essential use. Many stakeholders have offered opinions around the decision-making process and in particular on who should be responsible. ECHA's Committee for Socio-Economic Analysis (SEAC) featured as a suggestion from multiple industry respondents in a European Commission document inviting CARACAL members to answer specific questions on essential use. This suggestion has the support of AmCham EU who described SEAC's assessments as "*comprehensive, compared to a black and white decision*

[217] Ibid footnote 180
[218] Ibid footnote 196

on whether it is essential or non-essential".[219] However, an Austrian representative described SEAC and the Committee for Risk Assessment (RAC) as unfit to decide on essentiality, and suggested a new committee of sociology, ethics and cultural anthropology experts be developed.[220] ClientEarth replied to the same European Commission document inviting CARACAL members to answer specific questions on essential use stating SEAC should not be the primary decision maker.[221] The NGO believes the Commission and Member States should make the final decision under the "*scrutiny*" of the European Parliament.[222] An industry stakeholder held similar views, describing the difficulties governments may have deciding essentiality in democratic societies and free markets.[223] Cefic also highlighted the need for representatives "from across the stakeholder community" for legitimacy and transparency.

6.2.3 Concept Evolution

The set of essential use criteria will require periodical revisions depending on the depth of the criteria, as these factors may change as society develops. Perspectives and priorities can change swiftly, this has been apparent through the pandemic where we have seen the need for chemicals legislation to adapt quickly to societal needs. The European Regulation and Innovation Forum (ERIF) agrees the definition of essential would be expected to develop over time and noted the risks to innovation if the definition were to remain static and not evolve.[224] The argument for a dynamic and evolving set of criteria and the possible influence this may have on innovation is complex. The European Commission, amongst others has linked regulatory complexity or ambiguity to a decrease in innovation due to the uncertainty these factors contribute. A dynamic definition will add instability to the concept and a lack of predictability for industry, thus hindering their research and development strategies. However a static definition may restrict innovation to an outdated idea of essentiality, this may limit the space for ideation to only the current area considered to be essential. One way to remediate this limitation is to permit the use of substances in research and laboratory settings, in controlled environments with limited exposure routes. Alongside the permitted use of substances, the Commission's pledge to invest in innovation should be inclusive of substances not currently considered to be essential but with the possibility of essential and valuable future applications. Another factor to consider is the style of definition, a simplified set of criteria with flexibility would stand the test of time better than a precise set of criteria, but again this approach leads to ambiguity and uncertainty.

Alongside the possible development of the definition, any exemptions for essential use should be reviewed on a regular basis as they are under The Montreal Protocol. AmCham noted in their Position Paper that for the Commission to encourage the constant search for alternatives the label of "essential" cannot be permanent.[225] Theoretically, as viable alternatives are developed, substances which previously fulfilled the "essential use" criteria will no longer receive the derogation. The frequency with which these derogations are reviewed will influence the research and development activity within the space and could encourage or discourage the development of alternatives. The Montreal Protocol considers and reviews exemptions on an annual basis. The burden of proof is again on the applicant to support these reviews, to ensure no viable alternatives have been developed and the use is still deemed essential.[226] ERIF highlighted the reoccurring issue of regrettable substitution and linked the push for alternatives as a driver of this issue. Unless there is time and incentives for "rigorous" assessments of alternatives the net risk may be increased instead of lowered by regrettable substitution.[227] The high burden of proof resting on applicants may encourage many to look for alternatives, but as the ERIF has highlighted this drive for alternatives does not guarantee a safer product. It is key that alternatives are

[219] 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
[220] Ibid footnote 196
[221] This was in response to the question "*What are the challenges for the use of the concept? Who will decide on essentiality for society and how can this decision be made?"*
[222] 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
[223] Ibid footnote 176
[224] European Regulation and Innovation Forum, 2021, '*Essentiality', Better Regulation, And Management of Risk From Technologies Highlights Note 16*
[225] Ibid footnote 168
[226] Ibid footnote 186
[227] Ibid footnote 224

met with the same analysis as the substances they are replacing and undergo the same tests to identify the suitability of the substitution.

Below is a table summarising the possible costs and benefits of the most influential aspects of the essential use concept.

Table 6-1 Summary of the possible costs and benefits of the most influential aspects of the essential use concept.

Aspect	Outcomes	Costs	Benefits
Introduction of the concept of essential uses under REACH and across EU Chemicals Legislation under the extension of the GRA	Change in Regulatory Approach	Cost of Education/ training Increased regulatory costs – increase in employment demands Uncertainty – reduction in innovation Reduction in R&D Spending	Increase in protection of human health and the Environment First move competitive advantage
The defining of criteria	Option A A detailed, comprehensive set of criteria defined multiple stakeholders from across the sector.	A detailed application process with a heavy burden of proof on the applicant Possibility of a lack of flexibility and applicability to all sectors and uses – unnecessary restriction and loss of substances which could be deemed essential	Clear, predictable decision making which will boost innovation and competitiveness Clear set of guidelines for the deciding committee Inclusivity and coherence with the transition to chemicals that are safe and sustainable by design and strategies for a circular economy
	Option B A streamlined set of criteria to be used as guidelines defined by a select number of participants.	Uncertainty on regulatory decisions- negatively affecting innovation and competitiveness. Lengthy political decision-making process resting on the deciding committee A larger proportion of essential use applications leading to an increase in regulatory spending across the sector.	A more flexible approach allowing for a subjective application of the term essential. A flexible approach may allow for leniency towards substances vital for sustainable technology or the circular economy.
Method to determine essential uses	Option A Predefined list of Essential and Non-Essential uses	A restrictive list un-inclusive of all sectors may lead to unnecessary restrictions	Increase in clarity – boosting innovation and competitiveness
	Option B	Time intensive High burden on industry and the deciding committee	Tailored approach leading to a more appropriate application of essential uses

	Case-by-case assessment of essentiality	Lack of clarity -hindering innovation and competitiveness	
The decision making process	Option A ECHA's Committee for Socio-Economic Analysis (SEAC)	Lacking in expertise other than socio-economic	Respected for their comprehensive approach Established
	Option B Formation of a new committee (inclusive or exclusive of SEAC)	Committee would need time to become established, this may delay the implementation of the essential use concept. There may be controversy around the diversity of members causing delays in the regulatory process.	Opportunity to form a committee with expertise in sociology, ethics, economics and cultural anthropology. Opportunity to for a committee with knowledge across the chemical sector The new committee could produce more informed and tailored discussions on essentiality.
The evolution of the definition	Option A A Static definition.	Restrictive to developing technology Limiting towards innovation as the social perception of essential will change over time.	Consistent and predictable - boosting innovation and competitiveness
	Option B Dynamic definition with periodic evaluations and adjustments.	Increased difficulty in predicting your products "essentiality" in the future. Increased burden on the Commission to develop the criteria Increased burden on the committee to develop with the criteria	Development will promote new technological advances May lead to more appropriate essential use decisions. Encourages research into essential applications.

6.2.4 Coherence of the Concept

The Chemical Strategy for Sustainability states "*The criteria for essential uses of these chemicals will have to be properly defined to ensure coherent application across EU legislation, and will in particular take into consideration the needs for achieving the green and digital transition*." This is a key message in the CSS, all actions in the strategy must align with the green and digital transition including the concept of essential use. With the main outcome of the concept being the ban of all substances falling under specific hazard classifications[228] unless deemed essential, many have raised concerns around the need to recycle chemical substances and develop the chemical industry's circular economy. This extension of the GRA to substances included in articles or mixtures already in circulation will restrict the recycling and reuse of these materials limiting the industries efforts to produce a circular economy. The CSS does indicate that certain exemptions will be given to promote the recycling of materials but also states "*authorisations and derogations from restrictions for recycled materials under REACH are exceptional and justified"* indicating proof will be required to use these materials. These two initiatives are expected to on occasion reach a point of conflict as many substances in circulation are expected to be restricted after the extension of the GRA. The definition of essential would benefit from a recognition of this conflict and details on how a balance can be found between reaching a toxic free environment

[228] CMR cat. 1A,1B,2; PMT; vPvM; PBT; vPvB; ED; STOT SE/RE cat. 1,2; Respiratory Sensitisers cat. 1, 1A, 1B; Immunotox; Neurotox; Skin Sensitisers 1, 1A, 1B; Aquatic chronic cat. 1, 2.

whilst reusing materials already in circulation. With many companies currently developing their own strategies towards sustainability and circularity, including the Fragrance industry as a whole, added clarity on the intersection of the essential use concept and the aim for a green transition is vital for their success.

Alongside the hinderance this may pose to recycling and circularity, Cefic has commented on the possible influence the concept may have on the development of climate change solutions.[229] Cefic are not alone in this regard, ERIF also highlighted the risk this concept poses to technologies key to sustainable developments.[230] These concerns revisit the topic of essentiality development, if the need for sustainable development and the reuse of materials is included in the criteria of essentiality it can be expected that this factor of the definition will develop over time and be inclusive of new technologies for climate mitigation. Again the burden of proof will be on the applicant for these exemptions, this will add friction to the development of certain technologies. It can be expected that if a lengthy application process is required this will limit the innovation and restrict the evolution of certain technologies which could mitigate climate change. The CSS aims to address these concerns by "*supporting investments in sustainable innovations"* and investing in innovation and research programmes. However the CSS also states the extension of the GRA "*provides clear signals to all actors*" – "*on the types of chemical substances where innovation should be prioritised by the industry"* indicating the Commission would endeavour to encourage innovation away from restricted substances. This aligns with the transition to chemicals that are safe and sustainable by design, with the aim of encouraging companies to move away from using hazardous substances at all. If this initiative is successful then the essential use derogation will not be a prominent aspect of legislation, the use of the derogation would be minimal, and the impact of the concept would not be as significant. This idealist view does depend on the ability for all product sectors to evolve to be safe and sustainable which some would argue is not currently possible and thus whilst industry innovates and develops towards this aim, the essential use concept is expected to be influential.

6.2.5 Conclusions

The essential use concept holds the ability to dramatically alter the way EU chemicals legislation currently evaluates the value of a substance. The discussions over the next year to decide the criteria released by the Commission by the end of 2022 will be vital to the concept's success. With the lack of guidance on the concept so far, the concept could take on many forms, and of these incur many possible impacts. One divisive factor for the fragrance industry will be the detail provided on the essentiality of fragrances in consumer goods and the weighting on societal wellbeing and mood. There is substantial evidence for the influence of fragrances on wellbeing and mood therefore the coverage of these aspects of health in the definition will be important to the industry. The cultural importance of fragrances may also support the essentiality of fragrances if this can be proven in line with the essentiality definition. The considerations around cultural importance will also be key for fragrances ingrained in society and history. The committee formed to reside over these decisions will also influence the strength of these factors of essentiality. With the extension of the GRA to skin sensitisers not expected in the next ten years the fragrance industry may benefit from increased clarity as the essential uses concept is expected to be defined and established by the time the fragrance industry is most impacted by the extension of the GRA. However, as many has speculated proving the essentiality of consumer goods may prove difficult and the burden is expected to rest on the applicant leading many in the sector to consider alternatives.

[229] Ibid footnote 197197
[230] Ibid footnote 224

7 Conclusions

A targeted consultation with the fragrances industry and economic analysis reveals that changes to the GRA and CLP are likely to have significant impacts on the EU fragrance sector and the wider economy. In particular, **EU fragrance sector companies are estimated to lose between €0.9 billion and €2.0 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 €2.7 billion lower than the baseline, or 15% of their 2040 turnover.

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 and reformulation. For example, businesses have suggested that they would be able to substitute and/or reformulate around 33% of the portfolio of products that could be affected by the proposed policy changes. However, baseline product characteristics and performance are not guaranteed by these strategies, the outcomes of which might constitute entirely new products to be placed in the market, with uncertainty in how consumers will receive them.

The direct contribution of the sector to GVA would be between €0.3 and €0.5 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 fragrance sector to GVA would be between €0.8 and €1.7 billion lower per year over this period, on average. This would affect Member States differently, depending on the contribution of their fragrances sector to their overall economy.**

It is also estimated that operating expenditures would decline when compared to the baseline. These net reductions would be driven by the significant losses that are estimated to the size or operations of the EU fragrances market. At the same time, capital expenditure or investment would increase to sustain the needed levels of substitution and reformulation for the mitigation of further turnover losses. 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 around 50% on average over the period 2023-2040. Similarly, the 'ratio of OPEX to turnover' is estimated to increase against the baseline by between 3% on average over the same period. Further administrative costs would be incurred in the event a definition of essential use is introduced.

The changes to GRA and CLP would also affect the sector's employment. It is estimated that, by 2040, around 3,000 jobs in the EU fragrance sector would be lost against the baseline scenario, which is equivalent to 11% of the baseline fragrances workforce. **These impacts would have knock-on effects in the EU economy, which could lead to losing between 9,000 and 13,000 jobs by 2040 when compared against the baseline.**

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

Table 7-1 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 €0.8 billion per year on average against the baseline	A loss of €1.4 billion per year on average against the baseline	A loss of €1.7 billion per year on average against the baseline
Regulatory burden	An additional annualised burden of €258 million each year over the period	An additional annualised burden of €458 million each year over the period	An additional annualised burden of €373 million each year with a delay
Total employment contribution (*direct, indirect, induced*)	3,700 fewer jobs, on average, when compared to the baseline in any given year	7,000 fewer jobs, on average, when compared to the baseline in any given year	11,100 fewer jobs, on average, when compared to the baseline in any given year

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 fragrances currently on the market.

The **impact on downstream users from the fragrance sector** warrants **further exploration**. Among these, the detergents and the cosmetics industries are key.

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" if such a large number of products are removed from the market and where the definition of essential remains ambiguous.

To mitigate this, support would need to be provided to the fragrance 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 fragrance 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 fragrances 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.

Appendices

A1 Political and Legal Context

A1.1 Vertical Link Between Sector-Specific Legislation and the CLP Regulation

The International Fragrance Association (IFRA) is the global representative body of the fragrance industry. It seeks to represent the collective interests of the industry and promote the safe use of fragrances.

There is currently cross over between the CLP Regulation (Regulation (EC) No 1272/2008) and the Cosmetic Products Regulation (Regulation (EC) No 1223/2009), the Detergents Regulation (Regulation (EC) No 648/2004) and the Biocidal Product Regulation (Regulation (EU) No 528/2012), all of which may apply to products manufactured by IFRA members and affiliated partners upstream. As outlined above, the EU Chemicals Strategy for Sustainability (CSS) highlights the aim to amend CLP to include new hazard classes and criteria to fully address environmental toxicity, persistency, mobility, and bioaccumulation. These changes though will affect other linked regulations that implement CLP requirements through new hazard codes or to changes in the packaging.

A1.1.1 CLP Regulation

The Classification, Labelling and Packaging (CLP) Regulation (Regulation (EC) No 1272/2008) is based on the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The Regulation sets rules on the hazard classification of chemicals, how these hazards are communicated through labelling, and how the chemicals are packaged. CLP labels provide hazard information through pictograms, hazard statements, precautionary statements and other labelling elements[231].

A1.1.2 Link between CLP and the Cosmetic Products Regulation

The Cosmetic Products Regulation (CPR) (Regulation (EC) No 1223/2009) establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health[232]. Under the Regulation, a cosmetic product is defined as any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

The CLP Regulation (Regulation (EC) No 1272/2008) states that it applies to all substances and mixtures placed on the EU market, except where other community legislation "lays down more specific rules on classification and labelling". Due to this, the CLP Regulation does not apply to the labelling of most cosmetic products or mixture classification[233]. Instead, the Cosmetic Products Regulation has its own labelling requirements. The CLP Regulation does however apply to substances that are used as ingredients in cosmetic products.

Under the CPR there are no requirements for classification for intrinsic environmental hazard properties, as these are considered to be dealt with under REACH. There are also no requirements for environmental hazard labelling under the CPR. The labelling of cosmetics is aimed at end users and is based on potential risks to human health, which may be connected with the use of cosmetic products. The labelling is based on the listing of ingredients, with no requirement to provide hazard statements,

[231] European Commission. (2016). EU aligns its chemicals classification, labelling and packaging regulation to the 5th revision of UN GHS. Available at: https://ec.europa.eu/growth/content/eu-aligns-its-chemicals-classification-labelling-and-packaging-regulation-5th-revision-un-0_en
[232] European Commission (2021). Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast). Available at: EUR-Lex - 02009R1223-20210526 - EN - EUR-Lex (europa.eu)
[233] Chem Safety Pro (2017). GHS and Cosmetics. Available at: https://www.chemsafetypro.com/Topics/GHS/GHS_and_Cosmetics.html

hazard pictograms, or precautionary statements in accordance with CLP. There is also no mandatory requirement under the Cosmetic Products Regulation to create or make available a SDS for cosmetic product.

Chapter IV of the Cosmetic Products Regulation refers to restrictions for certain substances from use in cosmetic products. These include Annex II substances (prohibited substances); Annex III substances (restricted substances); Annex IV (colorants); Annex V (preservatives); and Annex VI (UV-filters).

The only link to CLP in the Cosmetic Products Regulation is that of substances classified as CMRs (carcinogenic, mutagenic or reprotoxic), with Article 15 of the Regulation directly referencing CLP classifications for the hazard identification of CMRs. In this case, there is a ban on CMRs being used in cosmetic products, but a derogation can be sought. Industry has criticised this approach to risk management of CMRs, as they are of the opinion that as the exposure and use of cosmetic products is known, and a Product Safety Assessment is carried out for all cosmetic products, then an automatic ban is not needed[234]. The use of the generic risk approach under Article 15 is discussed further in Section 3.3.

A1.1.3 Link between CLP and the Detergents Regulation

The Detergents Regulation (Regulation (EC) No 648/2004)[235] entered into force on 8 October 2005. The Regulation sets provisions for all detergents products placed on the market relating to biodegradability of surfactants used in detergents, the information provided to consumers via the labelling of detergents, the content of phosphates and other phosphorus compounds in detergents, and the information held by manufacturers that should be supplied to Medical Professionals and competent authorities on request. Under the Regulation, detergents are defined as “any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.”

The labelling of detergents is subject to both the Detergents Regulation and the CLP Regulation, as well as the Biocidal Products Regulation if the detergent contains a biocidal active substance and the detergent product has a biocidal claim. The Detergents Regulation also makes reference to the Cosmetic Products Regulation for the labelling of allergenic fragrances in detergents. Therefore, a detergent may be subject to numerous pieces of legislation regarding its labelling.

The labelling requirements under the Detergents Regulation differ to the labelling requirements under CLP Regulation, with both set of requirements needing to be met. Where detergents contain substances classified as hazardous, such detergent products will bear a label in accordance with provisions under CLP, in addition to a label in accordance with provisions under the Detergents Regulation. This can result in complex labels that provide too much information, some of which is duplicated (e.g. an ingredient may be listed twice), thus providing a confusing picture to consumers. Over-labelling is a problem as both the CLP Regulation and the Detergents Regulation require listing of allergenic perfumes and preservatives.

Classifications of detergents under CLP dictate the labelling on consumer, professional and institutional (maintenance and medical) detergent products. Feedback provided by a range of stakeholder groups as part of the 2017 Fitness Check indicated that the classification rules for mixtures under CLP are not considered to be adequate for the classification of consumer detergent products. This is partly due to classification under CLP being able to be based on the use of existing or new test data, on expert judgment or on calculations, which offers up several possible methods of classification. The choice of method can have a significant bearing on the outcome of the classification[48].

[234] European Commission (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 at: https://op.europa.eu/o/opportal-service/download-handler?identifier=7e26e205-18f9-11e7-808e-01aa75ed71a1&format=pdf&language=en&productionSystem=cellar&part=
[235] European Commission (2015). REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on detergents. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0648-20150601

A1.1.4 Link between CLP and the Biocidal Products Regulation

The Biocidal Product Regulation (BPR) (Regulation (EU) No 528/2012) concerns the placing on the market and use of biocidal products. The regulation not only impacts manufacturers and importers of biocidal products, but also affects article producers who use biocidal products to treat their products[236]. The BPR applies to:

- Active substances - a substance or a micro-organism that has an action on or against harmful organisms.
- Biocidal products - any substance or mixture, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
- Treated articles - Articles that have been treated with, or intentionally incorporating, one or more biocidal products.

Article 69 of the Biocidal Products Regulation (BPR) (Regulation (EU) No 528/2012) states that products sold under the BPR must be classified, packaged and labelled in accordance with the CLP Regulation[50]. Biocidal products must also be labelled with label elements specific to the BPR. These include:

- Trade name of the biocidal product;
- Name and address of the authorisation holder and authorisation number;
- Identity and concentration of every active substance;
- Nanomaterials contained in the product, if any, and any specific related risks (and following each reference to nanomaterials, the word 'nano' in brackets);
- Details of likely direct or indirect adverse side effects and any directions for first aid measures;
- Information on any specific danger to the environment particularly concerning protection of non-target organisms and the avoidance of a contamination of water;
- Type of formulation;
- Uses for which the biocidal product is authorised;
- Categories of users to which the biocidal product is restricted;
- Directions for use, frequency of application and dose rate, for each authorised use;

Where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the treated product, or the next potential entry of humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination methods and measures and duration of necessary ventilation periods of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use and transport;

- Conditions of storage (Art. 22 BPR);
- Directions for the safe disposal and, where relevant, any prohibition on the reuse of packaging;
- Formulation batch number or designation and the expiry date relevant to normal conditions of storage;
- SDS must be prepared for active substances and biocidal products.

Because biocidal products must comply with labelling requirements under both the CLP Regulation and BPR, this can result in complex labels that provide too much information, some of which is duplicated, thus providing a confusing picture to consumers. This labelling complexity creates increased space demands and requires more label (Stock Keeping Units - SKUs)[48].

A1.1.5 Global implementation of UN GHS

For the most part, the EU, US, Canada, China, Japan, Brazil and Australia have adopted the building block approach under the GHS, though there are some differences in the adoption of the health hazard classes. For example, with regard to the classification and labelling requirements for metal alloys and

[236] Chem Safety Pro (2017). How to Comply with EU Biocidal Products Regulation (BPR). Available at: https://www.chemsafetypro.com/Topics/EU/EU_biocidal_products_regulation_BPR_regulation_EU_528_2012.html

certain environmental hazard classes, Australia, the US, and Canada have yet to adopt any.[237] In particular, of the listed jurisdictions, the EU is the only one not to have adopted "Flammable liquids, Cat.4" and "Serious Eye damage/Eye irritation, Cat.2" building blocks.

Table A1-0-1 below illustrates these differences and the building blocks adopted by each respective country or region.

[237] DHI. (2020). GHS implementation - Compare building blocks. Available at: http://ghs.dhigroup.com/GHSImplementatationCompare.aspx

Table A1-0-1: GHS building blocks adopted by various countries, with those adopted in green and those not adopted in grey

Building blocks	EU	RU	US	CA	CN	JP	BR	AU
Physical Hazards								
Unstable explosives	✓	✓	✓		✓	✓	✓	✓
Explosives, Div1.1 - 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 - Cat. 3								
Oxidizing gas	✓	✓	✓	✓	✓	✓	✓	✓
Gases under pressure, Compressed, Liquefied, Refrigerated liquefied, & Dissolved	✓	✓	✓	✓	✓	✓	✓	✓
Flammable liquids, Cat. 1	✓	✓	✓	✓	✓	✓	✓	✓
Flammable liquids, Cat. 2	✓	✓	✓	✓	✓	✓	✓	✓
Flammable liquids, Cat. 3	✓	✓	✓	✓	✓	✓	✓	✓
Flammable liquids, Cat. 4		✓	✓	✓	✓	✓	✓	✓
Flammable solids, Cat. 1 - Cat. 2	✓	✓	✓	✓	✓	✓	✓	✓
Self-reactive substances or mixture, Type A - Type G	✓	✓	✓	✓	✓	✓	✓	✓
Pyrophoric liquids	✓	✓	✓	✓	✓	✓	✓	✓
Pyrophoric solids	✓	✓	✓	✓	✓	✓	✓	✓
Self-heating substances or mixtures, Cat. 1 - Cat. 2	✓	✓	✓	✓	✓	✓	✓	✓
Substances and mixtures, which in contact with water, emit flammable gases, Cat. 1 - Cat. 3	✓	✓	✓	✓	✓	✓	✓	✓
Oxidizing liquids, Cat. 1 - Cat. 3	✓	✓	✓	✓	✓	✓	✓	✓
Oxidizing solids, Cat. 1 - Cat. 3	✓	✓	✓	✓	✓	✓	✓	✓
Organic peroxides, Type A - Type G	✓	✓	✓	✓	✓	✓	✓	✓

Corrosive to metals	✓	✓	✓	✓	✓	✓	✓	✓
Desensitized explosives, Cat. 1 - Cat. 4						✓		
Health Hazards								
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, 1A, 1B, & 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, 1A, & 1B	✓	✓	✓	✓	✓	✓	✓	✓
Germ Cell Mutagenicity, Cat. 1A, 1B, & 2	✓	✓	✓	✓	✓	✓	✓	✓
Carcinogenicity, Cat. 1A, 1B, & 2	✓	✓	✓	✓	✓	✓	✓	✓
Reproductive toxicity, Cat. 1A, 1B, 2, & Lactation	✓	✓	✓	✓	✓	✓	✓	✓
STOT Single exposure, Cat. 1 - Cat. 3	✓	✓	✓	✓	✓	✓	✓	✓
STOT Repeated exposure, Cat. 1 - Cat. 2	✓	✓	✓	✓	✓	✓	✓	✓
Aspiration hazard, Cat. 1	✓	✓	✓	✓	✓	✓	✓	✓
Aspiration hazard, Cat. 2		✓			✓		✓	✓
Environmental Hazards								
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 - Cat. 4	✓	✓			✓	✓	✓	
Hazard to the ozone layer	✓	✓			✓	✓	✓	

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

A2 Substance to be Regulated List Methodology

Please note, The List of Substances to be Regulated was developed under contract for the European Chemicals Industry Council (Cefic) and was brought forward with the permission of Cefic for use in this assessment.

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 (e.g. lack of test data, missing CAS numbers) 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 Environmental Protection Agency (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 substance 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 Chemicals 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 A2-1. 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 A2-2. 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 A2-0-2 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 A2-0-2. 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 A2-0-3). 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 A2-0-3. 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:

2. The substance meets the criteria for classification as carcinogenic (category 2), or germ cell mutagenic (category 2) according to Regulation (EC) No. 1272/2008;
3. The substance meets the criteria for classification as additional category for "effects on or via lactation", according to Regulation (EC) No. 1272/2008;
4. The Derived-No-Adverse-Effect-Level (DNEL) is ≤µg/kg/d (oral, long term, general population), as derived following Annex I;
5. The substance acts as an endocrine disruptor in humans and/or wildlife species according to the WHO/IPCS definition of an endocrine disruptor."[238]

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.

Literature sources of PBT/vPvB and PMT/vPvM substances

UBA lists

[238] 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

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 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.

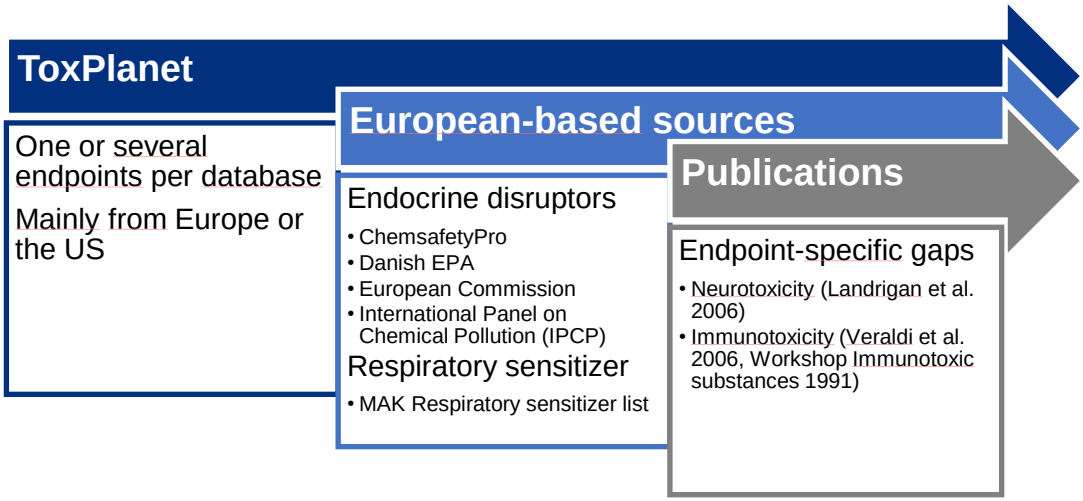
A recent report by KWR (2020) 'Persistence of gabapentin, 1H-benzotriazole, diglyme, DTPA, 1,4-dioxane, melamine and urotropin in surface water' tested the biodegradability of the selected

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 A2-0-1. 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 A2-0-1. 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 Environmental Protection Agency (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 A2-0-4 to Table A2-0-6 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.

Table A2-6 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 A2-0-4 to Table A2-0-6 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.

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 A2-0-4 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 A2-0-5 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 A2-0-6 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, sensitisers 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

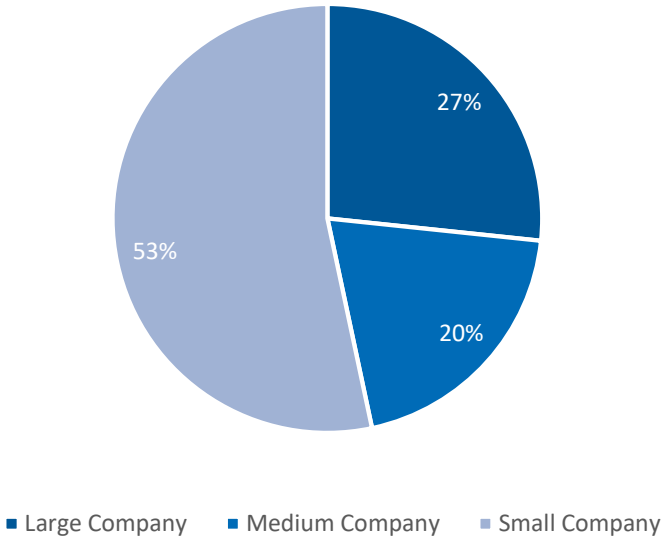
Adsorption / desorption

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 30 respondents to the consultations (both phases). Figure A4-0-2 provides the breakdown of respondents by company size.

Figure A4-0-2 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 products manufactured in the EU-27 (€ and tonnes) by product
- Volume of products imported and placed in the EU-27 market without any significant adjustments (€ and tonnes) by product
- Volume of products manufactured in the EU-27 (€ 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 are sold for their end use e.g., PC28 perfumes, fragrances[239]
- Percentage of total sales per sector
- Applicable hazard classification

[239] 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)

Information was requested for those products that fragrances companies surveyed place on the market[240] and not products that are purchased for internal use (e.g., raw materials or intermediates) in an effort to prevent double counting. Data was shared with Ricardo via an encrypted file sharing platform. Access to the data provided by each respondent was accessed by Ricardo only and could not be accessed by any third party or IFRA.

30 businesses responded to this consultation. The outputs provide us with an estimate of the size of the affected portfolio of products in the EU fragrances 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 5.

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 fragrances in the EU-27 provided in consultation 1 would indeed be affected, once businesses respond to the legislative changes e.g. through substitution and reformulation; and quantify key knock-on effects based on evidence collected from businesses directly, so far as was possible.

A four-part, 83-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 and/or reformulation; 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 and social 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 2-7. As outlined previously, the full list of questions have not been presented as numerous questions fed into the analysis of each impact sub-category.

[240] Ibid footnote **Error! Bookmark not defined.**

A5 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 5. In particular, three aspects are explored:

- Baseline estimation
- Knock-on effects to the wider economy
- Annualization of impacts

A5.1 Baseline estimation

This study defined and characterised how the EU Fragrances 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 Fragrances 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 Fragrances sector and the EU-27 economy, which would become the quantitative baseline against which the policy options would be assessed. Table 0-7 below outlines the selected indicators, based on their relevance and the evidence available from IFRA and Eurostat.

Table 0-7 Sectoral indicators selected for baseline characterisation[241]

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)

[241] 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 0-8provides an overview of these sources for each indicator.

Table 0-8 List of economic indicators and statistics used in the definition of a baseline and analysis of impacts

Indicator	Scope	Sources
Turnover	• Geo: EU-27 • Time: 2008-2019 • Other: fragrances sector, NACE Rev. 2 Code C20.53	• Eurostat Structural Business Statistics • The value of fragrance June 2019 – PwC & IFRA
Gross Value added (GVA)	• Geo: EU-27 • Time: 2008-2019 • Other: fragrances sector, NACE Rev. 2 Code C20.53	• Eurostat Structural Business Statistics
Intermediate consumption/ Opex	• Geo: EU-27 • Time: 2008-2019 • Other: fragrances sector, NACE Rev. 2 Code C20.53	• Eurostat Structural Business Statistics
Capital expenditure	• Geo: EU-27 • Time: 2008-2019 • Other: fragrances sector, NACE Rev. 2 Code C20.53	• Eurostat Structural Business Statistics
R&D	• Geo: EU-27 • Time: 2008-2019 • Other: fragrances sector, NACE Rev. 2 Code C20.53	• Cefic Facts and Figures 2021 and Country Reports
Regulatory burden	• Geo: EU-27 • Time: 2008-2019 • Other: fragrances sector, NACE Rev. 2 Code C20.53	• Cefic Facts and Figures 2021 and Country reports
Employment	• Geo: EU-27 • Time: 2008-2019 • Other: fragrances sector, (NACE Rev. 2 Code C20.53) 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[242] • Eurostat NAMA_10 • Eurostat NAIDA_10 • European Commission – Spring 2021 Economic Forecast

Some data gaps were identified, which rendered the data series incomplete for some of the economic indicators at the EU-27 fragrances sector level. These gaps were addressed by employing data available at the 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

[242] OECD (2018), GDP long-term forecast (indicator). doi: 10.1787/d927bc18-en (Accessed on 22 November 2021)

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 A5-0-9 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).

A5.2 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 fragrances sector have been estimated using an Input-Output methodology.

First, GVA measures the contribution that the EU-27 fragrances 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.

A5.3 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[243]. The following equation was employed.

Equation 0-1 $NPV = \sum_{t=0}^{n} \frac{C_t}{(1+r)^t}$, 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.

Equation 0-2 $AF = \mathrm{r}/[1-(1+r)^{-t}]$, 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.

A5.4 Weighting of future hazard classifications

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 weighting includes a number of sources of evidence, including the Registry of CLH intentions; the ED Assessment List and the

[243] European Commission, (n.d) *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

PBT/vPvB Assessment list . 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) and the average CLH without grouping;
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.

A6 Stakeholder Views on the Policy and Legal Implications

The proposed changes have received varying responses from key stakeholders, including Industry Association and NGOs. This Annex presents the views of these stakeholders on key political and legal implications of the extension of the GRA and addition of hazards to CLP.

A6.1 Global Political Context – Addition of Hazards to CLP

Endocrine disruption, PBTs, vPvBs, PMTs, immunotoxicity or neurotoxicity are not currently building blocks adopted through the global implementation of the UN GHS. Therefore, if the EU adds these as hazard classification categories, then its approach to hazard classification and communication will diverge from all other countries and regions.

In other words, the EU's new Chemicals Strategy for Sustainability will deviate from the international harmonisation of classification and labelling of substances, particularly as the UN GHS was substantially based on former EU classification and labelling standards. According to insights from intelligence network *Chemical Watch,* Industry representatives from the International Chemical Trade Association (ICTA) and American Chamber of Commerce to the EU (AmCham EU) have argued that because the CLP Regulation is designed to implement GHS standards in the EU, any policy changes should first be discussed at the international level to ensure consistency and ensure harmonisation of the GHS across jurisdictions[244]. Furthermore, in a statement released on 19 November 2020, German chemical industry body Verband der Chemischen Industrie (VCI) states that new hazard classes would undermine the global harmonisation of approaches to chemical restrictions[245].

The European Commission's 2nd Meeting of Competent Authorities Sub-Group on Endocrine Disruptors (CASG-ED) document, published 2nd July 2020, saw some backlash from industry with regard to potential changes to the rules for EDCs. The International Fragrance Association (IFRA) has expressed concern on the possibility to include criteria for endocrine disruption in the CLP Regulation on multiple occasions. IFRA reiterated that they cannot support such an inclusion for multiple reasons and stated that CLP is not intended to classify or regulate mode of action; both adverse effects and endocrine activity are needed for a substance to be an ED, and adverse effects are covered by CLP, so an ED classification would be redundant. IFRA also argued that REACH is the correct tool to identify and assess substances for ED properties, without being subjected to CLP. They note that "REACH has demonstrated its ability to identify EDs and manage associated risks, and the Substance Evaluation process allows for data generation in case of concern. Risk management is best achieved via sector legislation, taking the specifics of uses and exposure into account"[246].

A targeted stakeholder consultation in the context of a Fitness Check of EU legislation with regard to Endocrine Disruptors showed about half of respondents being in favour of a hazard category under the CLP Regulation to identify endocrine disruptors, while the other half was against the proposal, with respondents representing business associations, public authorities, companies, civil society, academia, and trade unions[247]. Specifically, although 93% of respondents considered the absence of harmonised criteria to pose a problem to a coherent approach in the EU for the identification of endocrine disruptors, about half of respondents did not believe that the lack of a hazard category covering endocrine disrupting properties in the CLP Regulation and/or GHS posed a problem for the coherent identification nor risk management of these substances. The majority of respondents were in favour of a combined hazard-based criteria and risk-based regulatory approach to address this.

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[244] Stringer, L. (2020). Keep CLP, GHS aligned under EU chemicals strategy, say industry groups. *Chemical Watch.* Available at: https://chemicalwatch.com/172461/keep-clp-ghs-aligned-under-eu-chemicals-strategy-say-industry-groups

[245] Chemical Watch. (2020). EU chemicals strategy: German chemical industry slams hazard-based emphasis

[246] CIRCABC (2020). 200902 IFRA EUROPE COMMENTS TO CASG-ED_2020_06. Available at: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/18eff9a6-2032-49fb-b92f-9ba82358cb05/details

[247] Joint Research Centre (European Commission). (2020). Targeted stakeholder consultation in the context of a fitness check of the EU legislation with regard to endocrine disruptors. Available at: https://op.europa.eu/en/publication-detail/-/publication/d1f4bbd9-6f13-11ea-b735-01aa75ed71a1/language-en

Furthermore, comments from the aforementioned statement by VCI suggest that new hazard classes would cause a decrease in the number of available chemicals in Europe as well as a sharp increase in compliance costs[248]. The changes to the CLP Regulation may result in trade barriers, as classifications will not be harmonised with those of other countries or regions. Other industry organisations such as ICTA and AmCham EU have stated that new hazard classes in the CLP Regulation which are not yet listed in the UN GHS will hamper a level playing field across countries, particularly as some countries implementing the GHS will need additional support in dealing with complex scientific criteria[249].

However, the EU can be said to have previously established global benchmarks with its chemicals legislation and commitment to other economic, social and environmental objectives, harnessing the world's most advanced latest scientific knowledge base on chemicals and setting a strong precedent for chemical risk management regulations in other countries[250,251]. The UN GHS, in particular, was substantially based and inspired on former EU classifications and labelling systems. Therefore, according to the NGO European Environmental Bureau (EEB), it can be argued that if the EU intends to champion chemical management globally, it must lead on new hazard classes, and aim for the rest of the world to follow[252]. Another observation supporting this argument is that experience with implementation of the GHS in one major trading partner or country has triggered implementation in a similar way thus far[253].

The harmonisation of chemical hazard classification criteria could therefore serve to strengthen the effectiveness and coherence of EU policy while sending a signal to other countries to adopt a similar approach. In particular, in the case of endocrine disruptors, proponents of the new hazard classification categories have argued that the same criteria should apply across relevant EU chemicals regulations as those for plant protection products and biocidal products, and that harmonised classification processes for new hazards will enable adequate risk management at the EU level[254,255]. For instance, NGO representatives speaking on behalf of the EDC-free Europe coalition at the Second Annual Forum on Endocrine Disruptors in Brussels praised the Commission for planning to introduce new hazard classes and help overcome the issue of information gaps for many substances. According to *Chemical* Watch, other NGOs such as the EEB have also welcomed the establishment of specific classification criteria for hazards such as immunotoxins and neurotoxins, given the increase in scientific knowledge on these substances in recent years[256]. That being said, various responses from industry suggests that risks from endocrine disruptors and potentially other hazard classes could be added to the existing framework under REACH, in full alignment with the WHO definition, by re-applying criteria established under the EU Plant Protection Products and Biocidal Products Regulations[257].

A6.2 The Generic Approach to Risk Management and Essential Use

As outlined in Section 3.1, the GRA is applied via REACH Restriction (Article 68(2)) for CMRs in consumer products, textiles and articles and for CMRs, PBT/vPvBs and EDs in some sector specific legislation. The Commission has committed to extending the generic approach to ensure "*that*

[248] Chemical Watch. (2020). EU chemicals strategy: German chemical industry slams hazard-based emphasis
[249] Stringer, L. (2020). Keep CLP, GHS aligned under EU chemicals strategy, say industry groups. *Chemical Watch.* Available at: https://chemicalwatch.com/172461/keep-clp-ghs-aligned-under-eu-chemicals-strategy-say-industry-groups
[250] European Commission. (2019). Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses {SWD(2019) 199 final}. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2019:264:FIN
[251] Squire Patton Bogs. (2020). Chemicals Strategy for Sustainability Heralds Most Significant Changes to EU Chemicals Regulation in 15 Years. Available at: https://www.squirepattonboggs.com/-/media/files/insights/publications/2020/10/chemical-strategy-for-sustainability-heralds-most-significant-changes-to-eu-chemicals-regulation-in-15-years/chemicalstrategyforsustainability.pdfhttps://www.lexology.com/library/detail.aspx?g=58ef3761-98c4-4a4f-877b-85725ce15b07
[252] Stringer, L. (2020). Keep CLP, GHS aligned under EU chemicals strategy, say industry groups. *Chemical Watch.* Available at: https://chemicalwatch.com/172461/keep-clp-ghs-aligned-under-eu-chemical-strategy-say-industry-groups
[253] 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 at: https://op.europa.eu/en/publication-detail/-/publication/7e26e205-18f9-11e7-808e-01aa75ed71a
[254] European Commission. (2020). Fitness Check on endocrine disruptors. Available at: https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_on_Endocrines_disruptors.pdf
[255] Ibid footnote 250
[256] Davies, E. (2021). EU industry 'alarmed' at perceived CLP divergence from GHS. *Chemical Watch.* Available at: https://chemicalwatch.com/233351/eu-industry-alarmed-at-perceived-clp-divergence-from-ghs
[257] The European Chemical Industry Council (CEFIC). (2020). Input Paper on the Chemicals Strategy for Sustainability. Available at: https://cefic.org/app/uploads/2020/09/Cefic-Input-Paper-Chemical-Strategy-for-Sustainability-CSS.pdf

consumers, vulnerable groups and the natural environment are more consistently protected, while still allowing for the use of these most harmful chemicals where proven essential for society".[258]

Key Points

- Member State competent authorities commonly indicated that the current risk management approaches should remain in their common form, and that they are well balanced (37%).[259]
- Industry most commonly thought the framework should be more orientated towards SRA.[260]
- NGOs and other civil society organisations most commonly thought the framework should be more orientated to the GRA.[261]
- Stakeholders from all categories have highlighted the need for greater flexibility and a more integrated and holistic view in assessing substances as groups.
- Concern from industry that the differences in risk management measures across legislation were not justified and that there is a need for the rationale behind the differences across the chemicals acquis to be made clearer. [262]

A6.2.1 Views of stakeholders on the current GRA

The current different approaches to risk management reflecting policy-specific considerations have been both criticised and accepted by different stakeholder groups.[263]

In the open public consultation as part of the 2017 Fitness Check of relevant chemicals legislation (excluding REACH), respondents were asked about their opinion on whether the chemicals legislation framework overall should remain the same or be oriented towards the SRA approach or the GRA. [264] The key responses are summarised below:

- **Member State competent authorities commonly indicated that the current risk management approaches should remain in their common form, and that they are well balanced (37%).** Member State governments and public authorities tended to have the view that the GRA approach enables a clear signal to be given regarding which properties of substances should be avoided, and therefore greater certainty and predictability. In contrast they viewed SRA as more costly for operators and not as predictable as GRA.

- **Industry most commonly thought the framework should be more orientated towards SRA.** Industry, and in particular larger companies, expressed a preference for the use of SRA, with 72% in favour of SRA. Whilst acknowledging that the GRA offers greater regulatory predictability and clarity, Industry highlighted that the GRA may result in illogical situations. For example, the GRA could lead to a ban in the use of ethanol in cosmetic products, whilst alcohol-containing food, beverages and perfumes would not be banned. It was also noted that to maintain innovation and competitiveness, the precautionary principle should not be overused. Industry commented that an SRA is generally more appropriate to determine the most effective risk management measure (whilst preserving societal benefits).

- **NGOs and other civil society organisations most commonly thought the framework should be more orientated to the GRA.** Although the most common response was for generic risk considerations (41%), 25% agreed that there should be more orientation towards SRA and 16% of respondents thought legislation should remain as it is. Areas for extension of the GRA were proposed, such as food contact materials, toys, furniture and certain construction materials. Also specific human health and environmental impact endpoints, that give rise to

[258] Ibid footnote 58
[259] Ibid footnote 32
[260] Ibid footnote 32
[261] Ibid footnote 32
[262] Ibid footnote 58
[263] Ibid footnote 58
[264] Ibid footnote 82

concerns equivalent to that of CMRs, PBT, and EDs[265], were highlighted as possible extensions of the GRA. SRAs were mentioned as being disadvantageously slow.

- **Citizens mostly did not have a view. Of those that did, their views were divided.** The majority of citizens (ca. 60%) did not know how to answer/did not provide an answer on these topics. Of those that did, opinions were divided with equal support for an increase in SRAs and an increase in the GRA. They also highlighted that SRAs are too slow.

Additional stakeholder views have been organised below into four main talking points; the GRA vs the SRA approach, the consequences of the GRA, and sector specific and substance specific views.

A6.2.2 Views Comparing the GRA and the SRA Approach

Many have expressed views on the way in which SRAs are conducted. For context, a substance can be assessed in an isolated context (substance-specific risk assessments) or as part of a substance group of chemicals with similar properties. It has been acknowledged that most hazard and exposure data needed are held by industry with analyses completed on single substances, and the hazard data available is usually on single substances. However, stakeholders from all categories have highlighted the need for greater flexibility and a more integrated and holistic view in assessing substances as groups. A grouping approach is seen as a way of improving the efficiency of SRAs, leading to more proportionate risk management. Grouping is also mentioned in the CSS. In this context the grouping approach is to be used before the GRA is fully extended. The CSS states that the Commission will "in the meantime, 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".

The fact that the efficiency of the risk assessment process could be improved has also been highlighted. For example, the costs to industry of replacing a substance could be avoided if it is clear what substances are likely to be banned.

A6.2.3 Views on the Consequences of the GRA

Member States and NGOs have expressed that the automatic triggers, as a consequence of the GRA, help prevent exposure to harmful substances quickly and efficiently. They argue it is important to consider that the costs of inaction are very high. However, in contrast industry stakeholders have highlighted that substitution can be expensive and resource intensive. The 2015 study on the impact of REACH on innovation, competitiveness and SMEs found that when substances entered the registry of restriction intentions, substantially more SMEs than large firms withdrew the substance from the market (17.2% compared to 5.4%). Follow-up interviews suggested that this action led to a number of activities, including using alternative substances where possible and carrying out research to develop new substances. It should be noted that it may also lead to a loss of business in terms of turnover or profitability for individual firms, indicating that the innovation as a result of regulatory action is complex. We may also see a different company moving into the space created by the company that withdrew their business. This is an important factor to consider as, even though industry may be required to innovate and substitute through regulation, this can be very costly and difficult to achieve. This is even more so if the required technologies or substances are novel.

Research has found that applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous or may be less toxic but carry a greater potential for release and exposure. Automatic bans on hazardous substances under the GRA require the immediate reformulation of products (although derogations exist for certain products). This incurs a cost and is why the GRA may be criticised as the more expensive approach. However, it must be noted that, if the substance is found to exhibit an unacceptable risk, the SRA would also result in a restriction and, where possible, reformulation or cease of manufacture.

[265] including neurotoxicity, immunotoxicity, terrestrial toxicity and persistent, mobile and toxic (PMT) substances.

Whether the current generic risk approach is affecting competition is also debated. For example, the existing implementation of a GRA to regulate EDCs in plant protection and biocidal products has been heavily criticised by World Trade Organisation (WTO) members. This is due to the fact that globally the EU regulatory system is the only one to implement scientific criteria to define EDs in legislation.

A6.2.4 Views on The GRA within Sector Specific Regulation

Prior to the 2019 Commission Staff Working Document on the Fitness Check, there was an existing concern from industry that the differences in risk management measures were not justified and that there is a need for the rationale behind the differences across the chemicals acquis to be made clearer. The lack of consistency was raised in the 2017 Fitness Check of the CLP Regulation and related legislation. In fact, the lack of consistency in implementation and enforcement of the risk management measures was identified by stakeholders as having the biggest negative impact on the functioning of the single market.

Under both Biocidal Products Regulation (BPR) and Plant Protection Products Regulation (PPPR), the GRA is used to address active substances that are CMRs, PBT/vPvBs and EDCs. Derogations exist under both pieces of legislation for carcinogens and reprotoxins, but the derogation conditions differ slightly. The BPR allows three routes to derogation under Article 5(2):

a) “the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst-case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;

b) it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

c) not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.”

In contrast, legislation on Plant Protection Products (PPPs) allows for a derogation based on “the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005”. Stakeholders have raised concerns about differences such as these. When comparing the case studies, used to evaluate the horizontal coherence of regulatory assessments for EDs across policy areas, it has been identified that the same substance(s) can be assessed differently under different frameworks. This is not specific to EDs and has been highlighted as a generic problem across EU chemicals legislation. This issue had been highlighted, as early as 2008, in the impact assessment report on the simplification of the “Cosmetics Directive”. This report discussed the interplay and lack of clarity of different pieces of legislation and the debate around when specific risk assessment or generic risk approaches are the most efficient. The Cosmetics impact assessment also mentioned that GRA risk prevention is commonly regarded as more effective and efficient if implemented from the top-down, e.g. via substitution.

A6.2.5 Views on the treatment of Specific Substances

NGOs have raised comments around the current regulation of CMRs. Currently, Category 1 CMRs are Restricted under REACH for consumer uses based on Article 68(2) generic risk considerations and in sector specific legislation such as the Cosmetic Products Regulation, often triggering automatic prohibition (bans). This does not currently apply for food additives, medical devices and veterinary products. In contrast, the GRA is not employed for all Category 2 CMRs for consumer uses. The generic risk approach for CMR cat. 2 is only used in regulations that cover vulnerable populations or uses that involve direct and difficult to control exposures. NGOs have highlighted that this is a gap, as the substances identified as having 'properties of concern', such as certain flame retardants and plasticisers classified as CMRs, are used in a range of consumer products, such as textiles, furniture and carpets.

Further to this the protection of children has been used as an example: NGOs have mentioned studies proving that chemicals, such as flame retardants and plasticisers, can be found in household dust. Inhalation of this dust is seen as an important exposure route for children. The generic risk approach under the Toy Safety Directive bans or restricts CMRs to protect children from potentially harmful exposures, and yet children do not only come into contact with toys, children also play with/on furniture in which CMRs are not automatically banned or restricted.

There have also been specific views on per- and polyfluoroalkyl substances (PFASs). Industry argues that currently, an SRA is a rational approach to regulating PFASs. Under REACH, the adoption of a Restriction requires authorities to demonstrate that the chemicals they seek to Restrict present "an unacceptable risk to human health and the environment". At present, the analysis requires the specificity of each chemical substance to be considered. There is not a one-size-fits-all restriction. Industry argues this is a rational approach considering Article 68 of REACH also requires authorities to consider socio-economic consequences of the proposed restriction, including the availability of alternatives. In contrast the European NGO community has been very vocal about the shortfalls of the current regulatory approach to PFAS. CHEM Trust has criticised the specific risk approach as leading to regrettable substitutions due to many PFAS being unregulated. CHEM Trust argues the current approach does not account for the future socioeconomic outcomes of the use of these substances, which is particularly relevant for persistent substances.

A6.3 Stakeholder views on the proposed changes

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. The CSS itself highlights that ample evidence and citizens' worries justify that the GRA should become the default for the most harmful chemicals. Furthermore, it has been stated that the 'essential uses' concept is compatible with current REACH provisions and can be used today.

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.

A6.3.1 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.

A6.3.2 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.

A6.3.3 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 an 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.

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.

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