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Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability

Mixture Assessment Factor (MAF) Case study

Case Study Report for the International Fragrance Association (IFRA)

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Contact:

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

T: +44 (0) 1235 753 104

E: becca.johansen@ricardo.com

Author:

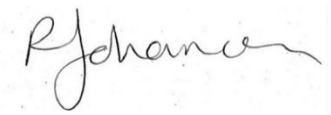
Rebecca Johansen, Brais Louro, Chris Hughes, Megan Griffiths, Emily Butcher, Marina Diez, Jacob Sendall (Ricardo) Joy Worden (Ricardo Associate)

Daniela Jeronimo Roque, Mishra Sanghamitra (Toxminds BvBA)

Approved by:

Rebecca Johansen

Signed



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Glossary

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

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

1 Introduction

1.1 Background to the Study

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

The European Green Deal[2] 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 by moving towards a toxic-free environment.

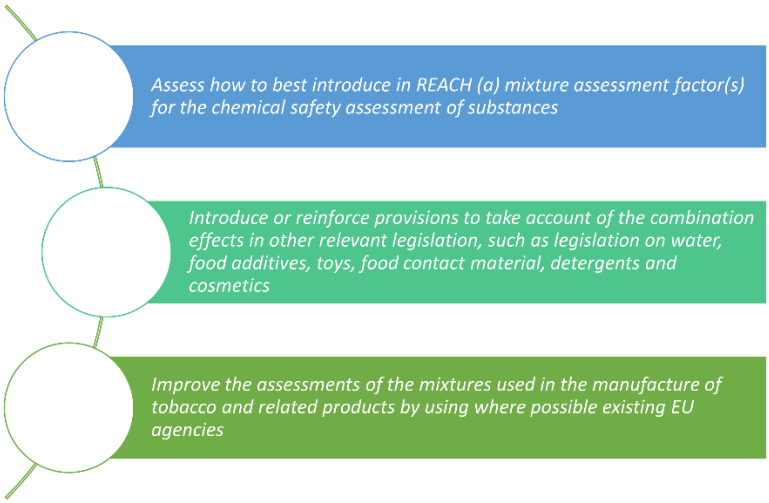
The European Union has one of the most comprehensive and protective regulatory frameworks on chemicals in the world, supported by the most advanced knowledge base globally. The manufacture and use of chemical substances within the EU must comply with a comprehensive legislative framework, which is increasingly becoming a model for safety standards worldwide, to ensure a high level of protection of human health and the environment[3], whilst also maintaining the functioning of the single market. This being said, studies[4,5,6] have noted the need to continue to improve current practices to ensure a higher level of protection.

The Chemicals Strategy for Sustainability (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 strategy contains around 80 action points or commitments, which seek to simplify and strengthen the chemicals legislative framework to build a comprehensive knowledge base that can support evidence-based policymaking, facilitate innovation of safe and sustainable chemicals, and further protect human health and the environment.

Figure 1-1 provides an overview of the commitments in the CSS related to ensuring the safety of human health and the environment with regard to unintentional mixtures.

[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://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN
[2] 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
[3] European Commission (2021) *Chemicals are everywhere*. Available from: https://ec.europa.eu/environment/chemicals/index_en.htm
[4] 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)
[5] Amec Foster Wheeler et al, 2017. Study supporting the Fitness Check on the most relevant chemicals legislation ("Fitness Check +")
[6] 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

Figure 1-1 CSS commitments related to ensuring the safety of human health and the environment with regard to unintentional mixtures



This case study analysis focuses on the introduction of a generic Mixture Assessment Factor (MAF) for the chemical safety assessments (CSA) of substances carried out under REACH registration.

In current regulation, Risk Characterisation Ratios (RCRs) for single substances are calculated and used to manage the risks that the manufacturing and/or use of these chemical substances pose to human health and the environment. “Safe use” for a single substance is defined below.

- When the Predicted Environmental Concentration (PEC) / Predicted No-Effect Concentration (PNEC) ratio is < 1, it is assumed that there is no significant risk associated with the environmental presence of the chemical.
- When the Exposure / Derived No-Effect Level (DNEL) ratio is < 1, it is assumed that the level of chemical exposure poses no significant risk to human health.

The MAF would be a factor by which the assessors would need to divide the regulatory thresholds for each individual compound. The aim is to reduce the exposure to individual substances, so that this may *account* for any **unintended mixture effects**. That is, when a MAF is introduced, the maximum RCR under which “safe use” can be demonstrated is a PEC/PNEC or Exposure/DNEL ratios equal to or below 1/MAF. This essentially generates a stricter definition of what may be considered safe.

The European Commission is currently undertaking an Impact Assessment (IA) on the options for introducing a MAF and the factor to be applied is yet to be decided. The use of a MAF has been considered by academia and Public Authorities for a number of years, with various values put forward[7,8,9]. Following review of this literature, this case study seeks to assess the potential business impacts of the introduction of a generic MAF of 10 for chemical safety assessments.

1.2 Study Aims and Scope

This study presents one case study to illustrate the potential impact that businesses may face from the application of a MAF of 10.

Access to six Chemical Safety Reports (CSRs) was granted to experts from Ricardo and their subcontractor ToxMinds BVBA, with four substances selected for further analysis covering a range of

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

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

[9] Tørsløv. J., Slothus. T., Christiansen. S. (2011) Endocrine disruptors: combination effects

low, medium and high business impacts. These CSRs were provided by the four Lead Registrants who performed them in order to have an easy and quick access to them.

The Ricardo study team developed a survey targeting these four substance cases. Given that only the Lead Registrant was able to be engaged per substance, in order to protect confidential business information, one case study was developed representing the total market and the average experience across these four substance cases in an attempt to illustrate the types and scale of impact that the EU's fragrance industry may face from the introduction of MAF [of 10].

1.3 Report Structure

The rest of this report is structured in the following sections:

- Section 2: Policy context
- Section 3: Methodology
- Section 4: Case study - technical analysis
- Section 5: Case study - business impact analysis
- Section 6: Conclusions
- Annex 1: Stakeholder consultation approach.

2 Policy Context

The current practice for risk assessment of chemicals in the EU is usually for individual substances, or under certain circumstances, mixtures intentionally added for particular uses. In reality, humans (workers and consumers) and the environment are exposed to unintentional mixtures of chemicals. Due to the wide variation and unknown nature of exposure over time, the risk posed is difficult to characterise. As such, the CSS put forward the need to "*assess how to best introduce in REACH (a) mixture assessment factor(s) for the chemical safety assessment of substances*". The introduction of a mixture assessment factor (MAF) aims to account for some of the uncertainty of mixture effects in risk assessment.

The risk of single substances to humans and the environment can be assessed using risk characterisation ratios (RCRs). RCRs are ratios between exposure levels and no-effect concentrations. For human health, RCRs are calculated using equivalent values: estimated exposure levels for a given exposure pattern, and derived no-effect levels (DNELs), see Equation 1. The DNEL value, i.e. the exposure level above which humans should not be exposed, is calculated by dividing a health effect dose descriptor (e.g. a no-observed-adverse-effect level) by assessment factors. When the effect is driven by a non-threshold mode of action, a no-effect level cannot be determined and hence a derived minimal effect level (DMEL) value is used in place of a DNEL value to derive a semi-quantitative RCR.

For the environment, these concentrations are the predicted environmental concentration (PEC) and predicted no-effect concentration (PNEC), see Equation 2. The PNEC, determined for each environmental compartment, describes the concentration of a substance below which adverse effects are unlikely to occur.

Equation 1 RCR for human health

$$RCR(human\ health) = \frac{exposure}{derived\ no{-}effect\ level}$$

Equation 2 RCR for the environment

$$RCR(environment) = \frac{predicted\ environmental\ concentration}{predicted\ no{-}effect\ concentration}$$

The RCRs for all possible exposures such as for all relevant routes of human health exposure, human populations, durations, and environmental compartments associated with each exposure scenario are used to quantitatively, or semi-quantitively, assess whether the substance is "safe" to use, and all of the risks of the substance are controlled.

RCR value is less than 1:

- It can be assumed that the exposure level of the substance poses no significant risk.
- Indicates that the exposure concentrations of the substance to humans or the environment are lower than the concentration that is expected to cause adverse effects; this therefore demonstrates "safe use" for the substance.

RCR value is greater than or equal to 1:

- It can be assumed that exposure concentrations exceed the threshold for effects. As such, the risk is deemed "unacceptable" and measures must be taken to reduce this value.
- Owing to the relationship between exposure and no-effect levels in a ratio form, this can be done by either lowering the exposure levels or increasing the minimum level at which no effects are expected.

The MAF multiplies the RCR by a generic factor, with the aim of covering any unintended cumulative or cocktail effects of mixtures by acting as an additional safety margin. The numerical value of the MAF is unknown at present. However, the potential application of a MAF would mean that some RCRs which

are currently less than 1 would now be elevated to greater than or equal to 1, meaning that “safe use” for that substance is no longer demonstrated. This essentially generates a stricter definition of what may be considered safe for use when considering unintended mixture effects from multiple exposures to multiple substances.

For this case study, a generic MAF of 10 has been applied to the current RCRs of selected chemical substances, resulting in all original RCRs of greater than or equal to 0.1 demonstrating an unacceptable risk, with these substances then in need of additional measures to reduce the adjusted value to less than 1. This exercise details the potential options available to registrants to reduce all RCRs for 4 case-study substances to below 1 if a MAF of 10 was introduced. The work forms the basis of a consultation with chemical companies to ascertain the economic impacts that the introduction of a MAF will have, a module that forms part of a larger Impact Assessment that Ricardo Energy & Environment have been contracted to conduct by the International Fragrance Association (IFRA).

3 Methodology

This section provides an overview of the methodology employed to consider the potential business impacts and knock-on economic implications that could result from introducing a generic MAF of 10.

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

Where possible, the methodology was inspired or based on the European Commission Better Regulation Guidelines and Toolbox, although this is a focused analysis of business impacts and associated economic implications, and thus it does not consider how other stakeholders may be affected and/or the broader social and environmental impacts.

- **Step 1: Technical review of Chemical Safety Reports** (CSRs). The four selected substances cover low, medium, and high potential economic impacts, thus representing the breadth of potential impacts on the EU chemicals industry (see Section 4.1). The implications of applying a MAF of 10 to the RCRs of each CSR were investigated. Experts in the study team considered the actions that the registrants may need to take in order to bring RCRs below 1 when a MAF of 10 was applied (i.e., below 0.1 before the MAF is introduced). The output of this step was a list of possible actions that registrants may wish to take to bring the original RCRs below 0.1 and thus continue supporting as many of the current uses as possible.
- **Step 2: Map and screen the business and economic impact categories.** A longlist of economic impacts was developed and screened, based on Tool #18 (identification of impacts) of the latest Commission's Better Regulation Toolbox[10]. From these, two business and economic impact categories were identified as likely to be significant for a more in-depth assessment. Across these impact categories, different types of economic costs and benefits were considered, primarily based on Tool #56 (Typology of costs and benefits) and a few indicators were selected to assess impacts quantitatively (see Table 3-1). Social and environmental impacts and, therefore, any indirect economic impacts driven by these, were not in scope of this exercise, which is focused on the fragrance industry and industry-driven economic effects.

Table 3-1 Sectoral indicators selected for baseline characterisation

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

- **Step 3: Consult stakeholders and gather evidence.** The Lead Registrant of the four selected substances was engaged as part of this project. This was a key and horizontal task that provided the evidence required to illustrate the potential impact of the application of a MAF of 10. The consultation activities and data analysis carried out in this Study were based on Tool #53 (Conducting consultation activities), Tool #54 (Analysing data and informing policymaking) and Tool #67 (Data identification for evaluation and impact assessment) of the Commission's

[10] Better regulation toolbox | European Commission (europa.eu)

Better Regulation Toolbox. These activities included a targeted consultation online survey, targeting the Lead Registrants for each of the selected substances. The online survey followed a similar approach to a recent Study by Ricardo for Cefic[11], further detailed in Annex I. When necessary, follow up conversations with respondents were held to ensure that their responses would be interpreted correctly.

- **Step 4: Create the one 'case substance'**: Due to the stakeholder engagement approach required for this project and given the limitations associated with confidential business information, a 'case substance' was created that represents the total market and average experience of the four selected substances, even if it does not refer to any specific substance available on the market. The 'case substance' embeds the insights from the responses of the registrants consulted.
- **Step 5: Define and characterise the baseline scenario against which to assess the MAF.** The study considered how the EU-27 market of the case substance would likely evolve 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 #60 (Baselines).
- **Step 6: Assess the business and economic impacts of the policy options.** Business and economic impacts were assessed for the case substance. The quantitative analysis was based on the Commission's Better Regulation Toolbox, e.g., Tool #57 (Methods to assess costs and benefits). The economic and statistical methods employed for the quantification of policy effects were selected based on the suitability for analysis of the evidence collected through a business survey, and the development of a case substance.
- **Step 7: Conclusions**. The quantitative and qualitative evidence on business and economic impacts for the constructed case substance was employed to present the implications of a MAF of 10. These implications have also provided a basis to develop insights and/or conclusions for consideration by policymakers as they continue to develop the options and ambitions set out within the CSS.

[11] Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf (cefic.org).

4 Case studies -Technical analysis

A team of experts from Ricardo and ToxMinds carried out a technical review of CSRs for four substances and considered the actions that registrants could take to bring a maximum number of RCRs below 1 if a MAF of 10 were applied (i.e., below 0.1 before the MAF is introduced). A description of the exercise and findings are provided in the following sub-sections.

4.1 CSR

The purpose of this exercise was to identify potential options that registrants could take to amend their CSR in order to bring a maximum number of RCRs below 1 with a MAF of 10 applied (i.e., below 0.1 before the MAF is introduced). Six CSRs resulting from CSAs were provided by IFRA members. Tonnage information, exposure scenarios, uses, hazard values, exposure assessments and resulting RCRs presented in the CSRs were investigated for the six substances to select four that represented a range of potential impacts (low, medium and high). The remaining two substances were excluded as their impacts overlapped with substances in the final selected four. These potential impacts were considered in terms of effort to bring affected RCRs back to acceptable levels or to reflect any potential restriction. The true impacts were difficult to predict without a detailed investigation of the CSAs, however, a rough idea of the potential scale of impact was determined. For the environmental section, the potential impact was allocated based on the number of RCRs greater than or equal to 0.1, the proportion of impacted uses/exposure scenarios, the types of environmental compartment affected (including man via environment), the number of impacted wide dispersive uses, and whether there was a high regional contribution. For the human health section, the potential impact was allocated based on the number of RCRs greater than or equal to 0.1, the impacted exposure routes and magnitude, the exposure modelling tools used per route (e.g. ECETOC TRA v3.1, ART 1.5, RiskofDerm 2.2.1., ConsExpo Web 1.0.7), the use of estimated / measured exposure values, the impacted life cycle tree component (e.g., formulation, consumer uses) and possible hazard refinements (e.g., toxicokinetics, higher tier studies).

Out of the six substances, four were used: two were used for both the environment and human health evaluations, and one each for only human health and the environment. A summary is provided in Table 4-1. Where possible the same substances were selected, but there was a disparity between the severity of the possible economic impacts as a result of actions taken to reduce the risk for human health and the environment, e.g., substance 2 was selected to be used in the human health evaluation, but no environmental RCRs of equal to greater than 0.1 existed for this substance, so thus it was excluded from the environmental evaluation.

Table 4-1: Summary of the 4 substances used for the environment and human health assessments as having potential low (“L”), medium (“M”) and high (“H”) economic impacts.

	REACH registered tonnage band	Environment	Human Health
Substance 1	≥1000 to <10,000	L	M
Substance 2	≥1000 to <10,000	N/A	L
Substance 3	≥1000 to <10,000	M	N/A
Substance 4	≥10 to <100	H	H

N/A = Not applicable

Exposure scenarios with RCRs greater than or equal to 0.1 were reviewed for options for businesses to reduce hazard or exposure to the extent that RCRs became less than 0.1 for all affected exposures for each use. It is assumed that businesses would take one or multiple actions within each of the following A-E types of responses defined by ECHA. In order of priority (ascending economic impact), these actions are:

A. Adjust values for Risk Characterisation Ratios without substantially changing the exposure assessment (e.g. review of the basic input parameters and the initial assessment strategy).
B. Revise some or all exposure scenarios based on existing data through refining/changing the assessment method or single input parameters.
C. Generate data (environmental testing, human health testing and/or exposure measurements) in order to review (lower) assessment factors or level of conservatism in exposure estimates.
D. Additional risk management measures to be implemented at professional/consumer user level.
E. Limit the use of the substance, with or without possible substitution (e.g., industrial user only, upper concentration limit on products, no use in water contact, etc.).[12]

For both the environment and human health, Option A was used to multiply all RCRs for all uses by a factor of 10. Theoretically, options A, B and C do not change the actual risks of the substance, but refine the RCRs, exposure, and hazard or exposure data, respectively, to increase the realism of the risk assessment; options D and E decrease the actual risks by reducing exposure and are hence seen as more severe responses. Option E is seen as a "last resort" whereby a reduction in actual tonnage or concentration of the substance is required to achieve safe use. However, the boundary between each of these options could be overlapping and an assessment may have to combine more than one option to refine the RCR by showing realistic conditions of use. Some assessments could also be limited to D and/or E options as the other potential options were not considered realistic or feasible by the registrants.

4.2 Environment

Following a review of each substance's CSR and assessment file, an Excel file for each substance was created, gathering the RCRs of greater than or equal to 0.1 for each use and relevant environmental compartment, as well as information about the substance itself (identifiers and physicochemical properties). Based on this information, three substances were selected as low, medium and high impact case studies for the environment.

The substance selected as being "low" impact (substance 1) following the introduction of a MAF of 10 was allocated so, primarily due to the low number of RCRs greater than or equal to 0.1 and the low proportion of impacted uses. Substance 3, deemed likely to incur a medium level of impacts, had a higher proportion of uses impacted and the number and severity of RCRs ≥ 0.1 was greater. The "high" impact substance (substance 4) had an even higher proportion of impacted uses, the largest number of compartments affected, and included man via the environment RCRs.

4.2.1 Action A

A MAF of 10 was applied to the entire set of environmental RCRs. For those RCRs where this application did not push the values above the threshold, no further actions were taken. For those RCRs now above the 0.1 threshold, actions B-E were considered.

4.2.2 Action B

Action B was used to present options to improve exposure scenarios based on existing data. The site tonnages and approach used to determine exposure estimates were reviewed for the potential to be made more realistic and refined to more company-specific values, i.e. could a company-specific site tonnage be used in place of more generic tonnages, and could an existing measured value or Specific Environmental Release Category (SpERC) replace a default Environmental Release Category (ERC). Under this step, the substance property input data was also reviewed, for example did the physicochemical properties seem appropriate and reliable, and was the substance a UVCB (substance

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

of unknown or variable composition, complex reaction products or of biological materials), which may affect the selection of input values.

For substance 1 ("low" impact for the environmental assessment), it was proposed that for the water emission, European Solvents Downstream Users Group (ESVOC), Cosmetics Europe and IFRA SpERCs could be used in replacement of ERCs, if deemed appropriate by the registrant(s). For a manufacturing use, this would reduce the water emission by a factor of 2,000, on condition that oil/water separation is used on site before discharge. Using a SpERC would reduce the water emission by a factor of 1.3 for a formulation use, and a factor of 25 for an industrial use of monomers for manufacture of thermoplastics. For another formulation use, no viable option was identified under Action B as an appropriate SpERC was already in place.

For substance 3 ("medium" impact), all affected uses already used SpERCs, however for one of the formulation or re-packing uses, it was proposed that a less generic SpERC could be used instead, if appropriate, to reduce the water emission by a factor of 10.

Similarly, for substance 4 ("high" impact), only one use (a formulation use) was identified as having potential to be improved through refined exposure estimates. For this use, a 16.7% reduction in daily site tonnage (achieved by increasing the number of emission days by 50 or by reducing the annual tonnage by 16.7%) would sufficiently reduce all impacted RCRs. Alternatively, the use of existing measured emissions to wastewater (0.1%) instead of the more conservative 0.2% emission assumed by the SpERC, would also fix the RCRs.

4.2.3 Action C

Unlike Action B which used existing data to refine exposure, Action C concerns the generation of new exposure data and extends to the generation of new hazard data too. As RCRs are ratios between exposure and hazard threshold values, RCR values can be reduced by a) decreasing the PEC or b) increasing the PNEC. The former involves measuring the exposure in the relevant emission routes that the RCR is sensitive to, for example freshwater RCRs will be sensitive to water emissions while agricultural soil RCRs may be sensitive to water emissions and/or air emissions. For each affected RCR, the emission route that needed to be improved was supplemented by whether measurement was scientifically feasible, and the magnitude of the reduction required to sufficiently reduce the RCR.

The PNEC is derived by dividing a dose descriptor (e.g. concentration that causes an effect in 50% of the test organisms (EC50) or the no-observed effect concentration (NOEC) or concentration that causes an effect in 10% of the test organisms (EC_{10})) by an assessment factor. In principle, increasing the PNEC may be achieved by reducing the assessment factor through conducting additional testing (e.g. higher tier chronic tests or tests with more organisms representing different trophic levels). The use of less stringent assessment factors account for the increased confidence in the data when additional information is generated. . However, whether the PNEC will actually increase by additional testing depends on the outcome of each additional study, e.g. the reduced assessment factor could be outweighed by an even lower, new dose descriptor. For soil and sediment PNECs, there was also the option of using new test data to replace modelled data based on the Equilibrium Partitioning Method (EPM), taking consideration of whether an additional assessment factor needed to be used for adsorptive/low degradability substances[13]. It was also considered whether substance property data, e.g. water solubility, could be improved by new testing, however this was not identified as an option for any of the substances.

For every affected use of substance 1, it was suggested that the assumed emissions to wastewater could be refined via a) discharge chemical oxygen demand (COD) measurements, or b) discharge analysis for the substance. For the two impacted formulation uses, where agricultural soil was the only environmental compartment impacted by the MAF of 10, a third option was to generate toxicity test data to increase the soil PNEC. The existing soil PNEC values had been derived based on the equilibrium

[13] ECHA Guidance on information requirements and chemical safety assessment. Chapter R.10: Characterisation of dose [concentration]-response for environment.
https://echa.europa.eu/documents/10162/17224/information_requirements_r10_en.pdf/bb902be7-a503-4ab7-9036-d866b8ddce69?t=1322594768638

partitioning method, therefore soil tests with three trophic levels *may* improve the soil NOEC, and only an assessment factor of 10 would need to be applied to the NOEC.

The toxicity data for substance 3 was already based on adequate experimental data. Hence, the only options for refining the assessment based on new data were to measure discharge COD or analyse the discharge for the substance, in order to refine the assumed emissions to wastewater. These two options were applicable to all the affected uses with the exception of the consumer use, whereby no options were identified under Action C as measured data was already used to calculate water emissions.

For substance 4, most of the impacted uses could again potentially be fixed if the wastewater emission estimates were refined by using measured data, from either discharge COD measurements or discharge analysis for the substance. For manufacturing, where only man via environment RCRs were affected, it was proposed that the assumed emission to air could be refined using volatile organic compound (VOC) measurement, although an 80% reduction would be required to reduce the RCRs sufficiently. No appropriate options were identified for one of the formulation uses (release to water already having been measured during onsite monitoring) and all of the consumer uses. The generation of toxicity data was not identified as an improvement option for any of the uses for substance 4, as chronic NOEC values for water already existed and appeared valid.

4.2.4 Action D

Most exposure scenarios assume the implementation and use of risk management measures (RMMs) to control the amount of substance released in wastewater, air emissions or sludge application. However, as this may not always be the case, or more efficient RMMs may supplement/replace existing RMMs, this action considers whether additional RMMs are feasible for the substance properties and emission route. The Diamonds 3 software (Exposure Control Efficacy Library (ECEL v3.0)) and the Cefic RMM library were consulted to determine the most appropriate technology for removal of substances from water and air, as well as the expected efficiency of these. RMMs were filtered based on the relevant physicochemical properties of the substance (water solubility, vapour pressure), biodegradability, emission route (air or water) and ERC (1-3 or 4-7).

Following the search, it was considered that water RMMs, such as those employing adsorption techniques to remove contaminants, may be used to reduce water emissions for all affected uses of substance 1. The application of Sewage Treatment Plant (STP) sludge to land also falls under Action D, as this is a route by which RCRs to agricultural soil and man via the environment can be affected. A water RMM alone would reduce the RCRs sufficiently in all the impacted environmental compartments (including agricultural soil), however for the two uses (both formulation) where agricultural soil was the only impacted compartment, it was also suggested that stopping application of STP sludge to soil could be used instead.

For substance 3, using water RMMs (e.g. adsorption) to reduce water emissions addressed all the impacted RCRs, apart from the affected consumer use, for which RMMs are not applicable. There were no soil RCRs affected for substance 3 so the cessation of sludge to soil application was not considered. Similarly, the use of adsorption-based water RMMs was suggested for the majority of the affected uses for substance 4. This was not the case for the manufacturing use, whereby reduction of air emissions was the target to reduce the man via the environment RCRs; it was proposed that additional air RMMs (such as wet scrubber) could be used. RMMs were not applicable for the affected consumer uses.

4.2.5 Action E

This is the final step possible to reduce the RCRs, reducing actual local tonnages at site, and involves a physical restraint on the substance as opposed to the refinements detailed under Actions A-D. For each substance, it was calculated what the maximum site tonnage per year would need to be to fix each RCR (i.e. calculated for each environmental compartment for every impacted use). For each use, the lowest maximum daily site tonnage/largest required reduction was selected to cover all affected environmental compartments for that use. The percentage reductions in daily site tonnage required for all the RCRs for each use to remain below the threshold ranged from 16.7% (formulation) to 67% (industrial use of monomers for manufacture of thermoplastic) for substance 1; from 40% (consumer end-use) to 91% (formulation or re-packing) for substance 3; and from 16.7% (formulation) to 93%

(formulation, and formulation or re-packing) for substance 4. While some of these larger reductions in tonnages are unlikely to be feasible, they may be the only option if Actions A-D are not possible. Substances 3 and 4 both had consumer uses affected.

In addition to the RCRs for the individual uses, substance 3 and 4 also had affected RCRs for local exposure due to all wide dispersive uses (combined for all emission sources). Action E was the only option available to fix these RCRs; substance 3 required a 40% reduction in annual tonnage, while substance 4 required a 65% tonnage reduction.

4.3 Human Health

All the substances selected for the assessment had exposures via inhalation, dermal and oral routes. The substance selected as being “low” impact (substance 2) following the introduction of a MAF of 10 had scope for refinement on exposure aspects. The substance deemed likely to incur a “medium” level of impact (i.e., substance 1) had a moderate number of processes impacted but had scope for refinement on both hazard and exposure aspects. The “high” impact substance (i.e., substance 4) had most of its processes impacted, with scope for refinement on both hazard and exposure aspects.

Each substance-specific CSR/assessment file was reviewed and converted into an Excel format to conduct the assessment with a MAF of 10 (including the substance name, identifier, routes, long versus short, systemic versus local, tools versus measured). Under the scope of the current MAF assessment, the scenarios were reviewed to determine the different theoretical options under Actions A, B, C and D, which could be explored before proceeding to Action E. Some of the options under Action A, B and C (hazard) may have a generic impact helping to refine all process categories (PROCs)/product categories (PCs)/article categories (ACs), while some other actions under Actions B and C (exposure) and D were PROC/PC/AC specific. However, the feasibility of implementing these theoretical possibilities, which were aimed at being reflective of the realistic use conditions, required confirmation by the individual registrants. It is also critical to mention that the theoretical possibilities suggested as part of the MAF assessment are non-exhaustive and only exemplary of the possible ways for refining the risk assessment.

4.3.1 Action A

Action A was used to review the accuracy of the baseline data selected for the hazard and exposure assessment and identification of the impacted PROCs/PCs/ACs. Under this step, both hazard and exposure-related basic input parameters (e.g., water solubility) selection and strategies (e.g., point of departures, implementation of saturated vapour concentration) were reviewed to see if the most up to date ECHA recommendations were implemented. The overall qualitative/quantitative assessments were also checked for possible improvements.

The baseline data of the three scenarios was considered to be appropriate and there was no further scope for refinement under Action A (except for substance 2 where a qualitative assessment for skin sensitisation was suggested based on current classification). In terms of impacted uses following application of MAF of 10, substance 1 had 55% of the processes impacted for combined relevant routes, while substances 2 and 4, had 34% and 91%, respectively.

4.3.2 Action B

Action B, which was to refine based on existing data, was split between hazard and exposure assessments options. For the hazard assessment options, the absorption or point of departure (POD) data used for the DNEL calculations were reviewed to identify the possibilities of refinement. Under the exposure assessment option, Tier 1 theoretical refinement options were explored such as the reduction of the duration of the activity, the use of Sector-Specific Workers Exposure Descriptions (SWED)/ Specific Consumer Exposure Determinants (SCED) and/or the possibility to use higher tier exposure modelling tools. These options were not mathematically implemented and therefore were considered as “potential refinement” actions requiring final validation and assessment by the registrants.

For both substance 1 and substance 4, some refinement possibilities could be identified for the hazard assessment parameters (e.g., dermal absorption). Conversely, no scope for refinement was identified for substance 2. Regarding the exposure assessment parameters, there was scope for refinement for every substance by modifying the exposure parameters (e.g., duration of activity, implementation of industry associations SWEDs/SCEDs) and implementing or modifying higher tier tools assessment. However, the feasibility of implementing the theoretical options were still to be evaluated by the registrant.

4.3.3 Action C

Unlike Action B which used existing data to refine exposure, Action C concerned potential new exposure and hazard data when appropriate. The DNEL is derived by dividing a dose descriptor (e.g., the no-observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL) by an assessment factor. Thus, possibility of increasing the DNEL by reducing the assessment factor through conducting additional testing (e.g., higher tier chronic tests or tests with relevant routes of exposure) was explored. The use of less stringent assessment factors in general accounts for the increased confidence in the data when additional information is generated. It was also considered whether substance property data (e.g., log Kow, vapour pressure) could be improved by new testing, however, this was not identified as an option for any of the three substances. The possibility of refining the absorption data used for the DNEL calculations, by generating a dermal penetration and/or a toxicokinetic study was also explored. In addition, the possibility of having more realistic exposure values with the help of biomonitoring studies via the appropriate route of exposure was also considered as a signification refinement option. Nevertheless, all the above actions or possibilities may have a relatively higher economic impact compared to the actions explored under Actions A and B. Also, the option to generate higher tier data, simply due to the implementation of MAF 10, may lead to an undue burden on the registrant if not triggered by the REACH requirements for the relevant tonnage band. Generation of higher-tier data is subject to the approval of a testing proposal which is a lengthy process and thus can lead to delays in the fulfilment of registration requirements. The use of additional in vivo testing would, however, result in trade-offs with the EU's commitment to reduce or discourage animal testing.

For the hazard assessment options for substance 1 (medium impact) and substance 4 (high impact), the generation of dermal absorption and toxicokinetic study or higher tier toxicology studies (if available in future) may help to refine the DNELs. However, this is not a certain refinement option as the outcome of the study may or may not be favourable. For substance 2 (low impact), toxicokinetic and higher tier toxicological studies were already available, and the substance has a harmonised classification. For the exposure assessment options for substance 1 and substance 2, the generation of biomonitoring is not recommended at this stage but may be explored in future. For substance 3, the generation of biomonitoring data could be explored for the dermal route. However, while biomonitoring may be an option for refining the exposure values, it may be challenging for some types of substances, including fragrances, which are naturally present in the environment.

4.3.4 Action D

Most exposure scenarios assume the implementation and use of RMMs to control the dermal, inhalation (and oral) exposure to workers and consumers. However as more efficient or higher tier RMMs may supplement or replace existing RMMs, this action needs consideration, whether the suggested RMMs are feasible based on the substance properties and exposure route.

For substance 1 and substance 2, a possibility of refining the Tier 1 RMMs/PPEs (e.g., respiratory protection, room ventilation) and/or higher RMMs/PPEs (e.g., use of drum pump or higher effectiveness gloves) or combinations of different RMMs/PPEs was foreseen. For substance 3, only the possibility of refining some of the higher RMMs/PPEs (e.g., use of drum pump, gloves or respiratory protection) was suggested for workers. Generally, the prescription of respiratory protection or full working shift glove protection may be considered an additional burden on the workers in addition to the already existing RMMs/PPEs applicable. Increased surveillance will be required to ensure implementation, which will in turn increase the economic impact of MAF.

4.3.5 Action E

This is the final type of action defined by the ECHA methodology to reduce the RCRs by modifying the percentage of the substance in preparation and involves restricting the use of the substance in specific challenging processes. As an outcome, the assessor had to limit the upper concentration in products.

Only substance 1 and substance 2 had possibilities for refinement by reducing the percentage of the substance in preparation for some of their PROCs. For substance 4, this refinement was not a foreseen viable option, as decreased concentration would not improve the assessment if a Tier 1/factor approach was kept.

However, for some substances, the reduction of the percentage of the substance may not be realistic or a feasible option, due to a loss of the technical function. The alternative actions, which could be explored in these cases, would be restrictions of the substance at a process scale (e.g., transfer of substance at dedicated facilities only), use scale (e.g., an industrial use only), market scale (e.g., limited to certain sectors of use like detergents only). In case the restriction of the substance is also not considered as a feasible alternative, then substitution of the substance would be the last resort.

To conclude, the proposed actions under the current scope of MAF assessment are only exemplary theoretical possibilities, which was based on the review of the available information and limited understanding of the described conditions of uses. A more realistic assessment along with the feasibility analysis of the proposed options was undertaken by the registrants during the economic assessment.

4.4 Outcomes

The table below gives an overview of the impacts and refinement options for each substance if a MAF of 10 is applied.

Table 4-2 Outcome overview of the impact and options for human health and the environment for Substances 1-4 if a MAF of 10 is applied

	Human Health		Environment	
Substance	**Impact**	**Options for refinement**	**Impact**	**Options for refinement**
1	• Inhalation route: 37% • Dermal route: 11% • Oral route: 0% • Combined routes: 55%	**A** (adjust RCR values without substantial modifications): • Baseline data appropriate; no scope **B** (revise based on existing data): Refine exposure parameters (e.g., duration of activity), • Implement or modify higher tier assessments. • Some scope for refinement of dermal absorption. **C** (generate data): • Some scope for refinement – Dermal absorption and toxicokinetics studies, higher tier tox studies (if available in future) may help refining DNELs • While biomonitoring may	• Manufacture, formulation and one industrial use • Aquatic, sediment and soil RCRs	**B** • Possible alternative SpERCs for some formulation use **C** • Site-specific measurements of water emissions Additional toxicity testing to refine soil PNEC **D** • Additional water RMMs • Stop application of STP sludge to soil **E** • Reduce actual site tonnage by up to factor 3

	Human Health		Environment	
Substance	**Impact**	**Options for refinement**	**Impact**	**Options for refinement**
		be an option for refining the exposure values, it may be challenging for some types of substances. • **D** (additional RMMs): • Potential refinement on Tier 1 RMMs/PPEs (e.g. respiratory protection, room ventilation) and/or higher tier RMMs/PPEs (e.g. drum pump) or combinations of RMMs. **E** (limit the use of the substance): • Limit percentage of substance in preparation.		
2	• Inhalation route: 21% • Dermal route: 15% • Oral route: 0% • Combined routes: 34%	**A** (adjust RCR values without substantial modifications): • Baseline data appropriate; no scope **B** (revise based on existing data):		

	Human Health		Environment	
Substance	**Impact**	**Options for refinement**	**Impact**	**Options for refinement**
		• Refine exposure parameters (e.g., duration of activity, vapour pressure at elevated temperature), • implement industry associations SWEDs, • implement higher tier tools assessment • No scope for refinement of DNELs. **C** (generate data): • Not much scope for refinement – TK and higher tier tox studies are already available • Substance has harmonised classification. • Biomonitoring not recommended at this stage; maybe explored in future **D** (additional RMMs): • Potential refinement on Tier 1 RMMs/PPEs (e.g. respiratory		

	Human Health		Environment	
Substance	**Impact**	**Options for refinement**	**Impact**	**Options for refinement**
		protection, room ventilation) and/or higher tier RMMs/PPEs (e.g. engineering controls or containment) or combination of RMMs **E** (limit the use of the substance): • Limit percentage of substance in preparation		
3			• Formulation uses and main consumer use • Aquatic and sediment RCRs	**B** • Possible alternative SpERC for one formulation use **C** • Site-specific measurements of water emissions • Refine user-defined PNECoral (UVCB substance) **D** • Additional water RMMs **E** • Reduce actual site tonnage by up to factor 10 • Reduce tonnage of main consumer use by 40%
4	• Inhalation route: 38% • Dermal route: 79% • Oral route: 0% • Combined routes: 91%	**A** (adjust RCR values without substantial modifications): • Baseline data appropriate; no scope **B** (revise based on existing data):	• Manufacture, formulation, consumer and combined wide dispersive uses • Aquatic, sediment, man via environment RCRs	**C** • Site-specific measurements of water and air emissions **D** • Additional water and air RMMs **E** • Reduce actual site tonnage by up to factor 15 • Reduce tonnage of consumer uses by up to 75%

	Human Health		Environment	
Substance	**Impact**	**Options for refinement**	**Impact**	**Options for refinement**
		• Refine exposure parameters related to measured values conditions (e.g., duration of activity • Implement or modify higher tier assessments • Some scope for refinement of hazard assessment input data (e.g., dermal absorption). **C** (generate data): • Some scope for refinement - dermal permeability or toxicokinetics studies or higher tier tox studies (if available in future) may help refine DNELs. • Biomonitoring recommended for the dermal route **D** (additional RMMs): • Potential for refinement of Tier 1 and higher tier RMMs/PPEs		

	Human Health		Environment	
Substance	**Impact**	**Options for refinement**	**Impact**	**Options for refinement**
		E (limit the use of the substance): • Limiting percentage of substance in preparation not foreseen		

5 Case Study – Business impacts

This section describes the analysis of the baseline of the business for the case substance; the likely response from businesses if the MAF were introduced; and the potential costs and benefits driven by the impact on the EU fragrances sector.

Due to the stakeholder engagement approach required for this project and given the limitations associated with confidential business information, a '**case substance**' that **represents the total market and the average experience of the four selected substances** was created, even if it does not refer to any specific substance available at the market. The 'case substance' embeds the insights from the responses of the registrants consulted.

5.1 Baseline

The group of registrants consulted placed between 1.6-2.1 million tonnes of the case substance and its mixtures on the market, generating between 1.0-2.0 billion euros in turnover, and contributing around 400 million euros in GVA to the EU-27 economy in 2019. The case substance would primarily have consumer, professional, formulation and re-packing, and manufacturing uses affected.

Without any further policy intervention, the registrants estimate that their turnover could grow between 3%-6% per year, on average, over the coming decades. These businesses employ a total of 1,775 to 3,600 people (full-time equivalent) in the EU-27, which is estimated to grow between 1%-3% per year, over the timeline. These businesses also make capital investments of dozens of millions of euros and purchase goods and services worth hundreds of millions of euros each year from other businesses in the EU-27 and internationally. As such, they have a notable economic footprint.

5.2 Business response to the introduction of MAF

The technical team of experts in chemical safety assessments and CSRs considered the options that the registrants of the case substance may have to respond to the introduction of a MAF of 10, employing a framework developed by ECHA.

Registrants were able to identify a diverse range for actions across Types B, C, D and E to respond to MAF of 10 for human health and the environment. Most registrants consulted identified the need for some actions type E, i.e., to reduce their use of the substance with or without substitution and/or reformulation. Registrants also identified a wide range of actions across Types B, C and D. All of these are summarised as follows:

- **Type B:** Revise some or all exposure scenarios, e.g., use SpERC instead of ERC for water emissions, use existing measured emission to wastewater data instead of a more conservative SpERC, increase emission days from 250 to 300, adjust duration of activity, user higher tier exposure modelling tools, etc.
- **Type C:** Generate new testing data to review the assessment factors or level of conservatism in the exposure estimates, e.g., toxicity test data to increase soil PNECs, updated emissions data etc.
- **Type D:** Introduce additional RMM to reduce emissions, e.g., including tier 1 or higher tier RMM/ PPE, etc.
- **Type E:** Reduce site tonnage and withdraw the substance from some uses with some opportunities for substitution (30%-40% net withdrawal of substance from the market on average).

The registrants also identified that their clients would be affected by similar challenges. In fact, they estimate that, despite having introduced measures to address the effects of MAF, these clients would reduce their purchases partially or completely over the period.

There is uncertainty around registrant's ability to substitute and/or reformulate. All registrants consulted expressed concerns about the challenges of the processes they would need to embark on to substitute at scale, especially in the short term. However, they did identify some limited opportunities, with one respondent suggesting that around a third of their affected business could be 'replaced' with substitutes. Other registrants also identified that there could be a need to move parts of their business outside the EU.

Table 5-1 summarises the main business impact scenario developed based on the case substance registrants' responses to the online survey and follow-up conversations, and the key uncertainties.

Table 5-1 Impact scenarios and uncertainties

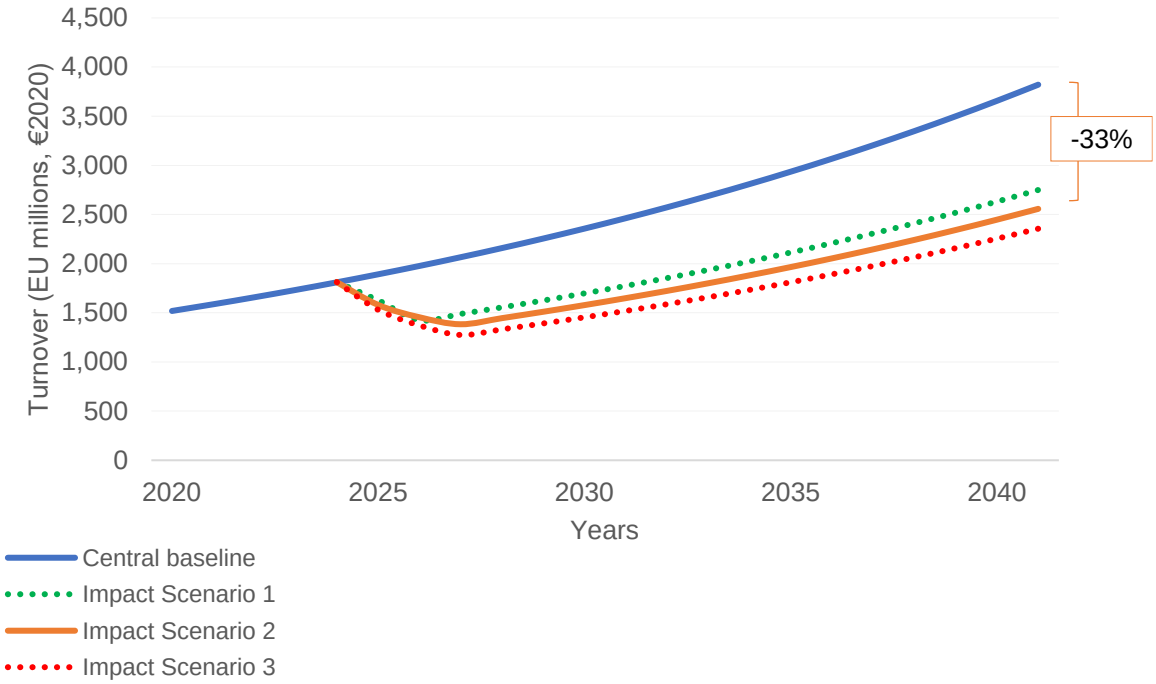
Main business impact scenario	Key uncertainties
*The registrants consulted would generally **continue processing and/or manufacturing the substance in the EU-27, whilst also taking the following actions:*** • *Revise some or all exposure scenarios* • *Generate new testing data to review the assessment factors or level of conservatism in the exposure estimates* • *Introduce additional RMM to reduce emissions* • *Reduce site tonnage and withdraw the substance with some substitution (around 30%-40% net withdrawal, on average) as clients reduce their purchases of the product*	*These business responses and implications are **uncertain**. Therefore:* • *The lower bound impact would consider the best-case scenario from business responses.* • *The upper bound impact assumes a worst-case scenario with significant net withdrawal of products and associated business activity, albeit respondents suggest they would keep the bulk of their current business activity in the EU-27.*

Given the inherent uncertainty with regards to the downstream user response and the associated costs, consultation respondents selected a range of values in response to questions on turnover and employment. **Impact scenario 2** reflects the midpoint of the response ranges and **impact scenario 1 and 3** reflect the lower and upper bound respectively. The responses were sense checked against the average values of the sample and some manual adjustments made when required.

5.3 Impacts on the EU fragrances sector and knock-on economic implications

The total annual sales value for the case substance is estimated to be between 1.0-1.5 billion euros lower in 2040, with a central estimate of around 1.3 billion euros (or 33%) lower when compared against the central baseline scenario. There is some uncertainty. Businesses downstream would also face regulatory and cost pressures both related and unrelated to the MAF and, as a result, are estimated to reduce their demand of the products. The results and estimated uncertainties are shown in Figure 5-1 below.

Figure 5-1 Estimated impact of MAF on the turnover of registrants (or estimated turnover losses against the central baseline)[14]



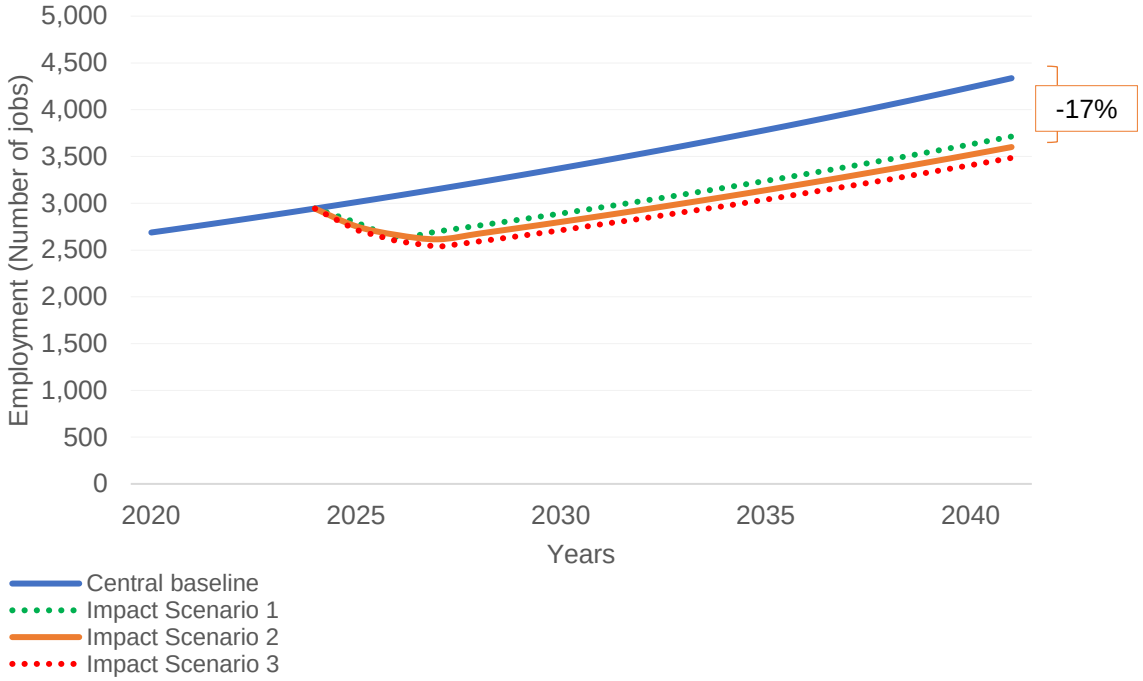
These implications on the case substance's market could **disrupt the European supply chain for the case substance**. For example, the substitution of the case substance for an alternative could lead to lower product performance, having consumer implications not only on choice but also on the accessibility and usefulness of the products they marketed. These implications could lead to more significant knock-on effects on the EU-27 economy.

Employment in the EU-27 by the consulted registrants is estimated to decrease by between 650-850 jobs in 2040, or a central job loss of around 750 (or -17%) by 2040 when compared to the

[14] Considering additional uncertainties with regards to the baseline projections, the case substance's market in the EU-27 could face a decrease in annual sales ranging from 500 million euros (against the low impact scenario 1) to around 2.7 billion euros (in the high impact scenario 3) against their respective baselines in 2040.

baseline. Figure 5-2 below shows three impact scenarios based on the estimated uncertainties, compared to this central baseline.

Figure 5-2–Estimated impact of MAF on the employment supported by the registrants (or estimated loss of employment against the central baseline)



These emerging results also illustrate a negative, direct impact on the sector's contribution to EU-27 GDP by 2040. The direct contribution to GVA of registrants would be between 300-400 million euros lower than the baseline in 2040. They also **capture a negative impact on the global competitiveness** of the substance manufacturers in the EU-27.

There are multiple other uncertainties with an ex-ante impact analysis such as this, including how other regulatory developments, international market dynamics, and research and innovation may affect these industries, etc. These uncertainties are likely to be significant and could not be estimated for, and thus are not captured in this Study.

6 Conclusions

A targeted online consultation and interviews of the Lead Registrants of four selected substances, which were packaged as a "case substance" due to data limitations, and a rapid economic analysis reveal that the introduction of a generic MAF of 10 could have substantial implications on the fragrance industry, with knock-on implications across the supply chain and wider economy.

The economic analysis was based on the assumption that a MAF of 10 would be introduced to the chemical safety assessment of a 'case substance'. Through a technical assessment, a range of possible actions for registrants were identified that could keep their RCRs below 1 in a context of MAF of 10 (i.e., "safe for use" in this new regulatory context, when accounting for exposure to multiple substances from multiple sources and the combination effects of these unintended mixtures). Registrants were also consulted on which of these actions they would likely take, which in summary included:

- Revising some or all exposure scenarios;
- Generating new testing data to review the assessment factors or level of conservatism in the exposure estimates;
- Introducing additional RMM to reduce emissions; and/or
- Reducing site tonnage and withdrawing the substance with some level of substitution (around 30%-40% net withdrawal, on average) as clients reduce their purchases of the product.

The total market for the "case substance" is estimated to be affected negatively, with a central estimate of 1.3 billion euros (or 33%) in turnover losses in 2040, when compared to the baseline scenario. These impacts would only be exacerbated by the additional regulatory burden that the registrants would face and would have direct implications on the EU-27's GDP –potentially resulting in direct losses of hundreds of millions of euros in value added–. The use of additional higher tier in vivo testing in order to reduce the RCRs would, however, result in trade-offs with the EU's commitment to reduce or discourage animal testing and present complexities for substances that are used in cosmetic products.

Further, the effects on the fragrances industry would also result in potential job losses in the EU-27 and a worsening of the global competitiveness of the EU-27 industry. As a result, supply chains would be affected and potentially disrupted, which would have additional negative economic implications across the EU.

To mitigate these potential business and economic implications, policymakers may wish to provide a clear implementation roadmap, consider a more targeted approach to addressing unintentional mixtures, and explore the use of additional mechanisms be that financial or regulatory, and/or allows for more time for registrants and other businesses to respond to the proposed policy changes in a way that would facilitate innovation and allow for new, more sustainable products to be brought to the market.

These conclusions are associated with the impacts on the EU chemicals businesses as a result of the introduction of MAF. 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.

A1 Stakeholder consultation approach

This annex provides additional details of the methodology employed to consult businesses as to the potential effects of the introduction of a MAF of 10. The consultation activities included targeted stakeholder online surveys, which were based on Tool #53 (Conducting consultation activities) and Tool #67 (Data identification for evaluation and impact assessment) of the Commission's Better Regulation Toolbox.

Evidence and views from the registrants are key to understand the potential implications of adopting a MAF of 10. Without their input, it would not be possible to rapidly consider the scale of the business implications.

One registrant for each of the four selected substances was contacted. Based on their answers, the case study substance was constructed and analysed.

The targeted stakeholder online survey sought was designed to elicit evidence and informed views from businesses in four parts and 61 questions as follows:

- Part 1 asks for data of the respondents, in terms of their size, main regions of operations, etc.
- Part 2 seeks to form a baseline, including of their current business operations associated with the substance and related mixtures, expectations of said business without any further policy changes, as well as high-level implications of the existing EU chemicals legislation.
- Part 3 considers direct business responses in the EU-27 and associated costs and benefits over at least 10 years from the adoption of MAF. This builds on the technical analysis of CSRs.
- Part 4 gathers information on other economic impacts that may be relevant, primarily qualitative (e.g., global competitiveness).

Responses to part 1 and part 2 of the survey especially were employed to develop a baseline against which the business implications of applying a MAF of 10 could be assessed for the case study. Evidence of the following indicators was collected for each substance, either for 2019, annual averages over the 2015-2019 period, or estimations of how these variables may change over the next 10 years if the MAF were not implemented:

- Volume of the substance of interest that is used and/or manufactured by the registrant (in tonnes and in millions of euros of turnover)
- Employment (number of employees) supported by the registrants of the substances of interest
- Core uses (e.g., manufacturing, use at industrial sites, formulation and re-packing, professional use, consumer use) of the substances and their mixtures (in tonnes or millions of euros in sales value)
- Operating expenditure or OPEX (in millions of euros)
- Annual average level of capital investment or CAPEX (in millions of euros)
- Annual average level of Research & Development (R&D) expenditure (in millions of euros) and the percentage of annual average R&D expenditure dedicated to discovering alternatives in the face of increasing regulation.

Responses to part 3 especially were used to identify the preferred potential business action(s) for each relevant use (manufacturing, use at industrial sites, formulation and re-packing, professional use, consumer use) that would mitigate the business impacts of applying a MAF of 10 and the potential one-off and recurring costs from implementing these actions.

The potential impact of business responses requested the following information:

- Where relevant, the level of substance or product withdrawal that would be required for the uses that would no longer be supported when a MAF of 10 is applied, and the extent to which other alternatives could replace or substitute the uses of the substances under review.
- Registrants were also asked to consider the extent to which downstream users (i.e., their customers) may reduce their demand of these substances and its mixtures, taking into account that downstream users may also be affected by the application of a MAF of 10.
- Based on this evidence or understanding, registrants were also asked more explicitly to provide their estimates of the extent to which average annual turnover, employment, OPEX, CAPEX,

R&D impacts may evolve each year over 10 years from the adoption of a MAF of 10, when compared to 2019 levels.

These requests followed different approaches to elicit evidence and informed views from businesses in a way that allows the project team to compare and contrast the impacts expected from an analysis of responses and review, adjust and/or qualify the results as required. For example, survey respondents were asked to provide their 2019 turnover and their estimated turnover growth over the next 10 years in the absence of the MAF (i.e., the baseline). Based on this baseline, businesses were asked to consider how they might respond to the MAF as follows: the actions they would need to take, including product or substance withdrawal, the extent to which there might be possible alternatives that could substitute or replace the market of the current substances, and how downstream users may behave, given these changes and the application of a MAF of 10, which may also affect them directly.

Following this, businesses were also asked, explicitly, to provide an estimate for how the adoption of MAF 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 substance and potential business responses.

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

In addition, follow-up conversations with two respondents were undertaken to review the responses constructively, understand the underpinning evidence and ensure the team's effective interpretation.

Finally, it is noted that 2019 was taken as the baseline year for eliciting evidence of potential impacts from businesses through survey, as 2020 and 2021 are not considered representative of normal operating conditions of the EU chemicals sector due to the COVID-19 pandemic. This means that the information gathered referred to potential impacts with regards to 2019 business operations.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