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Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability

Case Study: Mixture Assessment Factor

Report for the European Chemicals Industry Council (Cefic)

Final Report for European Chemicals Industry Council (Cefic)

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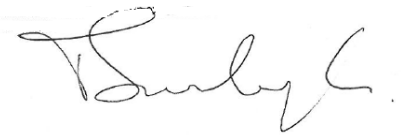

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Executive Summary

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

The European Green Deal sets 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. The CSS was launched in October 2020 to provide a new long-term strategy for chemicals policy, in line with the aims of the EU Green Deal.

The CSS strives for a toxic-free environment, where chemicals are manufactured and used in a way that can maximise their societal contribution but avoid causing harm to the environment or the population, now and in the future.

Policy Context

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

The risk of single substances to humans and the environment can be assessed using risk characterisation ratios (RCRs). RCRs are ratios between exposure levels and no-effect concentrations. For the environment, these concentrations are the predicted environmental concentration (PEC) and predicted no-effect concentration (PNEC), see Equation 3. The PNEC, determined for each environmental compartment, describes the concentration of a substance below which adverse effects are unlikely to occur.

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 4. 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.

Equation 1 Risk Characterisation Ratio for the environment

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

Equation 2 Risk Characterisation Ratio for human health

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

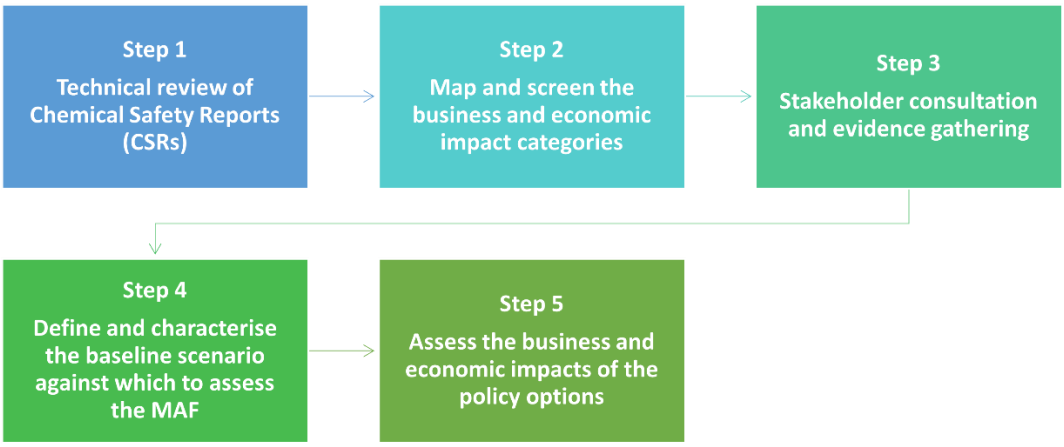
[1] European Commission (2020) *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment*, COM(2020) 667 Final. Available from: https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

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

The MAF multiplies the RCR by a generic factor, acting as a safety margin to cover any unintended cumulative or cocktail effects of mixtures. The MAF to be applied is yet to be defined and remains under assessment, but values ranging from 1-10 have been suggested by academia and authorities in the past[2][3][4]. For this exercise, a MAF of 10 has been applied to the current RCRs of selected chemical substances as a realistic scenario, resulting in all RCRs of greater than or equal to 0.1 demonstrating an unacceptable risk once the MAF has been introduced. The work forms the basis of a consultation with chemical companies to ascertain the business impacts that the introduction of a MAF would have. The case study forms part of a larger assessment performed by Ricardo for Cefic.

This study presents two case studies to illustrate the potential impact that businesses may face from the application of a MAF of 10. An overview of the methodology is provided in Figure 0-1

Figure 0-1 Overview of case study methodology



Access to six Chemical Safety Reports (CSRs) was granted to experts from Ricardo, with four substances selected as case studies that would cover a range of low, medium and high business impacts, thus representing the breadth of impact to the EU's chemicals industry. In the technical review of CSRs, 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.

Of these four substances selected for technical review, sufficient economic data was collated for two substances and these are presented in this study as Substance 2 and Substance 4. More detail on the case study substances carried forward in this assessment is provided in Table 0-1, which outlines the uses that are impacted by the MAF and the potential refinement options that have been identified.

[2] RIVM (2016) Addressing combined effects of chemicals in environmental safety assessment under REACH – a thought starter
[3] Sarigiannis. D. & Hansen. U. (2012) Considering the cumulative risk of mixtures of chemicals – A challenge for policy makers. Environmental Health. 11. 18
[4] Tørsløv. J., Slothus. T., Christiansen. S. (2011) Endocrine disruptors: combination effects

Table 0-1 Overview of Substance uses and CSR refinement options[5]

	Substance 1	Substance 2	Substance 3	Substance 4
REACH registration tonnage band	≥ 100,000	>1000	≥ 1 000 to < 10,000	>1000
Main uses	• Use as a monomer • Use as an intermediate	• Use as an intermediate • Organic solvent used in coatings, cleaning agents	• Polymer production and processing, rubber production and processing • Use as a fuel	• Use as an intermediate • Use of monomer in polymer production
List of uses	Industrial, professional and consumer	Industrial, professional and consumer	Industrial, professional and consumer	Industrial, professional and consumer
Human health Uses impacted (%)[6]	• Inhalation route: 95% • Dermal route: 43% • Oral route: Not relevant (no oral exposure expected) • Combined routes: 95%	• Inhalation route: 100% • Dermal route: Not relevant (qualitative assessment) • Oral route: Not relevant (no oral exposure expected) • Combined routes: 100%		• Inhalation route: 74% • Dermal route: Not relevant (no DNEL) • Oral route: Not relevant (no DNEL • Combined routes: 74%
Human Health refinement options	**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 industry associations SWEDs/SCEDs,	**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, vapour pressure at elevated temperature), • implement industry associations SWEDs,		**A** (adjust RCR values without substantial modifications): • Baseline data appropriate; no scope **B** (revise based on existing data): • Refine exposure parameters related to measured values conditions (e.g., duration of activity **C** (generate data):

[5] 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.

[6] Percentage of uses which will be impacted by the MAF due to impact on human health for the substance. e.g. 95% of uses will be deemed unsafe for exposure via the inhalation route following the application of the MAF without refinement.

	Substance 1	Substance 2	Substance 3	Substance 4
	• implement or modify higher tier tools assessments. **C** (generate data): • Some scope for refinement – Dermal absorption study, higher tier tox studies (if available in future) may help refining DNELs; • Biomonitoring not recommended at this stage; maybe explored in future **D** (additional RMMs): • Potential refinement on Tier 1 RMMs/PPEs (e.g. respiratory protection, room ventilation) and/or higher RMMs/PPEs (e.g. drum pump) **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.)): • Limit percentage of substance in preparation. Combinations of B and D refinements could be considered	• implement higher tier tools assessment **C** (generate data): • Not much scope for refinement – DNEL based on IOEL; higher tier reproductive toxicity study although not available, it is not likely to influence the DNELs; • Biomonitoring not recommended at this stage; maybe explored in future **D** (additional RMMs): • Potential refinement on Tier 1 RMMs/PPEs (e.g. respiratory protection, room ventilation) and/or Higher RMMs/PPEs (e.g. engineering controls or containment) **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.)): • Limit percentage of substance in preparation		• Not much scope for refinement – Substance has hivarmonized classification; • TK and higher tier tox studies already available; DNEL based on OEL; • Original exposure assessment based on biomonitoring data; • potential refinements suggested in B and D maybe implemented and a new biomonitoring study maybe considered **D** (additional RMMs): • Potential RMMs/PPEs refinements in real conditions of use (e.g. Respiratory protection, LEV **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.)): • Limit percentage of substance in preparation
Environment Impact	• Manufacturing and five industrial uses • STP RCRs	• Formulation and two industrial uses • Aquatic, STP and soil RCRs	• Manufacturing and six industrial uses • Secondary poisoning and man via environment RCRs	

	Substance 1	Substance 2	Substance 3	Substance 4
Environment refinement options	**B** • Reduce assumed site tonnage by up to factor 10 • Possible alternative SpERC for formulation use **C** • Additional testing to refine PNEC (repeat limit test at higher concentration) **E** • Reduce actual site tonnage by up to factor 10	**C** • Site-specific measurements of water and air emissions • Refine sediment and soil PNECs through additional testing (currently EqP approach) **D** • Additional air RMMs for one industrial (downstream) use **E** • Reduce site tonnage (up to 65% reduction)	**B** • Reduce assumed site tonnage by up to factor 10 **C** • Site-specific measurements of water and air emissions • Refine user-defined PNECoral (UVCB substance) **D** • Additional water and air RMMs **E** • Reduce actual site tonnage by up to factor 10	

Baseline

Businesses registering the selected four substances were consulted and a sample of four or more respondents were secured for two of these substances.

Table 0-2 Baseline

	Volume placed on the market (tonnes/ year (2019))	Turnover (€/year (2019))	EU-27 GVA (€/year (2019))
Substance 2	0.2-12 million tonnes	140-320 million euros	c60 million euros
Substance 4	1-3 million tonnes	2.3-4.5 billion euros	c900 million euros

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

Business responses, impacts on chemicals industry and knock-on economic implications

The technical team of experts on CSA/ CSRs employed a framework developed by ECHA[7] to consider options that the registrants of the selected substances may have to respond to the introduction of a MAF of 10.

This was followed by a targeted online consultation and interviews with registrants of two different chemical substances to understand the actions that they would be likely to take in this policy scenario. Table 0-3 provides an overview of the actions that registrants identified for the two substances taken forward for the assessment of impacts.

Table 0-3 Impact scenarios and uncertainties

Case studies	Main business impact scenario	Key uncertainties
Substance 2	The registrants consulted would generally **continue manufacturing the substance in the EU-27, whilst also taking the following action:** • Updating risk assessments • Revising exposure scenario • Generating emission data • Introducing further risk management measures to reduce worker/professional exposure • Withdrawal of the substance (by up to 20% on average) as clients reduce their purchases of the product	The business responses and implications are **uncertain**. Therefore: • The lower bound impact would consider the best-case scenario from business responses. • As the majority of respondents would continue business activity in the EU-27, the upper bound impact assumes a worst-case scenario with some withdrawal of products and associated business activity.
Substance 4	The registrants consulted would generally **continue manufacturing and using the**	The business responses and implications are **very uncertain**. Therefore:

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

Case studies	Main business impact scenario	Key uncertainties
	substance in the EU-27, whilst they would take significant action: • Introduce further risk management measures to reduce worker/ professional exposure • Withdraw some products from the market (10% and likely significantly more) These registrants also estimate that their clients may reduce their purchases (by 10% or likely significantly more, on average).	• The lower bound impact would include a scenario where registrants are able to support most uses of the substance by introducing risk management measures. Limited product withdrawal with no possible substitution or downstream response would be expected. • The upper bound impact includes some registrants shutting down their business activity in the EU-27 and moving some or all abroad and importing a more final product.

Based on these potential business responses, a rapid economic analysis was carried out to estimate the implications of a MAF of 10 on the chemicals industry and knock-on effects across the supply chain and wider economy.

This analysis revealed that the adoption of a MAF of 10 and the resulting business actions would have substantial impacts on their business activity and the associated supply chains due to the need to withdraw substances from the market and the introduction of stricter risk management measures which may reduce demand from customers further down the supply chain, due in part to the large investment needed. These impacts would be exacerbated by the additional regulatory burden that the registrants would face and would have direct implications on the EU-27's GDP, potentially resulting in direct losses of billions of euros in value added; and result in potential losses of thousands of jobs in the EU-27. These estimated impacts are outlined in the Table 0-4 below.

Table 0-4 Overview of business and knock-on economic impacts as a result of the introduction of a MAF of 10 in 2040, when compared to the baseline scenario

Case studies	Annual turnover loss (Million Euros)	Annual turnover loss (%)	Employment losses (FTE)	Employment losses (%)	GDP 'losses' (EUR)
Substance 2	23-77 million euros lost	8%-28% lost	50-150 jobs lost	5-18% lost	5-20 million euros lost
Substance 4	0.6-5.3 billion euros lost	10%-80% lost	500-5,600 jobs lost	5-53% lost	0.2-1.4 billion euros lost

Further, these impacts may lead to a worsening of the competitiveness of the EU-27 industry and a shift towards increasing imports of final products, increasing the dependency on third countries for chemical substances and/or products previously manufactured and used in supply chains across the EU. As a result, supply chains worth hundreds of billions would be affected and potentially disrupted, which would have additional negative economic implications across the EU.

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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
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
CSR	Chemical Safety Report
CSS	Chemicals Strategy for Sustainability
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
DU	Downstream Users
DUCC	Downstream Users of Chemicals Co-ordination Group
EC	European Commission
ECEL	Exposure Control Efficacy Library
ECHA	European Chemicals Agency
ED	Endocrine Disruptor
ED ENV	Endocrine Disruption affecting the Environment
ED HH	Endocrine Disruption affecting Human Health
EFCC	European Federation for Construction Chemicals
ELOC	Equivalent Level of Concern
EPM	Equilibrium Partitioning Method
ERC	Environmental Release Category
EU	European Union
FEICA	Association of the European Adhesive & Sealant Industry
FTE	Full-time equivalent
GCL	Generic Concentration Limit
GDP	Gross Domestic Product
GRA	Generic Approach to Risk Management (Generic Risk Approach)
GVA	Gross Value Added
IOEL	Indicative Occupational Exposure Limit Value
LE	Large Enterprise
LEV	Local exhaust ventilation

Abbreviation	Definition
LOAEL	Lowest Observed Adverse Effect Level
MAF	Mixture Assessment Factor
MSCA	Member State Competent Authority
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
OPEX	Operating Expenditure
OSH	Occupational Safety and Health
vPvB	very Persistent, very Bioaccumulative
PBT	Persistent, Bioaccumulative and Toxic
PCN	Poison Centre Notifications
PEC	Predicted Environmental Concentration
PFAS	Perfluoroalkyl chemicals
PMT	Persistent, Mobile and Toxic
vPvM	Very Persistent and very mobile
PNEC	Predicted No-Effect Concentration
POD	Point of Departure
PP	Percentage point
PPE	Personal protective equipment
PROC	Process Category
RCR	Risk Characterisation Ratio
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	Regulatory Management Option Analysis
SCCS	Scientific Committee for Consumer Safety
SCED	Specific Consumer Exposure Determinants
SCL	Specific concentration limit
SE	Single exposure
SDS	Safety data sheet
SME	Small & Medium Sized Enterprises
SoC	Substance of Concern
SpERC	Specific Environmental Release Category
SRA	Specific Risk Assessment
STOT	Specific Target Organ Toxic
STP	Sewage Treatment Plant

Abbreviation	Definition
SVHC	Substances of very high concern
SWED	Sector-Specific Workers Exposure Descriptions
TK	Toxicokinetics
UNCED	UN Conference on Environment and Development
UN GHS	United Nations Global Harmonised System
UVCB	Unknown Variable Composition Or Biological Substance
VOC	Volatile Organic Compound

1 Introduction

1.1 Background to the Study

This case study analysis has been commissioned by the European Chemicals Industry Council (Cefic) to assess the business impacts to the European (EU) chemicals industry of selected actions from the EU Commission's (EC) Chemicals Strategy for Sustainability (CSS): Towards a Toxic-Free Environment[8]. This study shall feed into the Cefic response to the EU Commission's CSS Impact Assessments.

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

Chemicals play a fundamental role in the functioning of our daily lives. They protect our health, contribute to food security, and are the building blocks of the products that we rely on every day. As chemicals have wide dispersive uses and play such a key role in our daily lives there is a need to reduce harmful exposures, whilst also maintaining sustainable use. This is particularly true of chemicals which demonstrate hazardous properties such as those which cause cancer or gene mutation, affect the reproductive, endocrine or immune systems, are persistent, bioaccumulative, mobile or toxic to the environment. Exposure to these chemicals is a threat to human health and the planet as a whole, potentially contributing to global crises such as climate change, biodiversity loss and environmental degradation.[9]

The European Union has one of the most comprehensive chemical regulatory frameworks in the world. This knowledge base helps to inform regulatory actions in other regions and has become a model for the safe use of chemicals[10]. The EU has been successful in maintaining the functioning of the single market, whilst reducing the risks to human health and the environment. This being said, studies[11,12,13] have noted the need to continue to improve current practices to ensure a higher level of protection. As such, the CSS was launched in October 2020 to provide a new long-term strategy for chemicals policy, in line with the aims of the EU Green Deal.

The CSS strives for a toxic-free environment, where chemicals are manufactured and used in a way that can maximise their societal contribution but avoid causing harm to the environment or the population, now and in the future. The strategy contains around 80 action points 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.

A few commitments are included concerning the use of mixture assessment factor(s) (MAF) for the chemical assessment of substances. These are:

- *"Assess how to best introduce in REACH (a) mixture assessment factor(s) for the chemical safety assessment of substances;*
- *introduce or reinforce provisions to take account of the combination effects in other relevant legislation, such as legislation on water, food additives, toys, food contact material, detergents and cosmetics;*
- *improve the assessments of the mixtures used in the manufacture of tobacco and related products by using where possible existing EU agencies."*

[8] 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
[9] Ibid footnote 8
[10] A. Bradford (2020) *The Brussels Effect: How the European Union Rules the World*. New York: Oxford University Press
[11] 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)
[12] Amec Foster Wheeler et al, (2017). *Study supporting the Fitness Check on the most relevant chemicals legislation ("Fitness Check +")*
[13] 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

This case study analysis focuses on the introduction of a MAF for the chemical safety assessments 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. Risks are considered controlled for a single substance is where.

- 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 expand the level of protection, so that this may *account* for any unintended mixture effects. That is, when a MAF is introduced, the maximum RCR under which risks are considered "controlled" 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, when accounting for exposure to multiple substances from multiple sources and the combination effects of these unintended mixtures.

The MAF to be applied is yet to be defined and remains under assessment, but values ranging from 1-10 have been suggested by academia and authorities in the past[14,15,16]. This study therefore seeks to assess the potential business impacts of the introduction of the MAF of 10 for chemical safety assessments.

1.2 Study Aims and Scope

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

Access to six CSRs was granted to experts from Ricardo, with four substances selected as case studies that would cover a range of low, medium and high human health and environmental impacts, thus representing the breadth of impact to the EU's chemicals industry.

Of these four cases, sufficient data was collated for two and these are presented in this study as Substance 2 and Substance 4. More detail on the case study substances carried forward in this assessment are provided in Table 1-1.

Table 1-1 Case study substance details

	Case Study Substance			
	Substance 1	Substance 2	Substance 3	Substance 4
REACH registration tonnage band	≥ 100,000	>1000	≥ 1 000 to < 10,000	>1000
Main uses	• Use as a monomer • Use as an intermediate	• Use as an intermediate • Organic solvent used in coatings cleaning agents	• Polymer production and processing, rubber production and processing • Use as a fuel	• Use as an intermediate • Use of monomer in polymer production

[14] RIVM (2016) Addressing combined effects of chemicals in environmental safety assessment under REACH – a thought starter
[15] Sarigiannis. D. & Hansen. U. (2012) Considering the cumulative risk of mixtures of chemicals – A challenge for policy makers. Environmental Health. 11. 18
[16] Tørsløv. J., Slothus. T., Christiansen. S. (2011) Endocrine disruptors: combination effects

	Case Study Substance			
	Substance 1	Substance 2	Substance 3	Substance 4
List of uses	Industrial, professional and consumer	Industrial, professional and consumer	Industrial, professional and consumer	Industrial, professional and consumer

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

Currently, the risk of chemicals in the EU is usually assessed for individual substances, or sometimes intentional mixtures for particular uses. In reality, the environment, workers and consumers are exposed to unintentional mixtures of chemicals, the risk of which is difficult to characterise. As outlined in Section 1.1, one of the CSS's three actions to address chemical mixtures is for the Commission to "*assess how to best introduce in REACH (a) mixture assessment factor(s) for the chemical safety assessment of substances*". As it is not possible to identify and regulate every single possible combination of chemicals that humans and the environment may be exposed to from different sources over time, the introduction of a MAF aims to account for some of the uncertainty of mixture effects in risk assessment.

The risk of single substances to humans and the environment can be assessed using risk characterisation ratios (RCRs). RCRs are ratios between exposure levels and no-effect concentrations. For the environment, these concentrations are the predicted environmental concentration (PEC) and predicted no-effect concentration (PNEC), see Equation 3. The PNEC, determined for each environmental compartment, describes the concentration of a substance below which adverse effects are unlikely to occur.

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 4. 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.

Equation 3 Risk Characterisation Ratio for the environment

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

Equation 4 Risk Characterisation Ratio for human health

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

The RCRs for all possible exposures (i.e. for all relevant routes of human health exposure, human populations, environmental compartments, durations) associated with each exposure scenario are used to quantitatively, or semi-quantitively, assess whether the risk of the substance is controlled and the substance is "safe" to use. When the RCR value is less than 1, it is assumed that the level of substance exposure poses no significant risk, as this indicates that the concentrations of the substance that humans or the environment are exposed to are less than the concentration expected to cause adverse effects; demonstrating risks are considered "controlled" for the substance. When this value is greater than or equal to 1, it is assumed that exposure concentrations are higher than the threshold for effects, and as such the risk is deemed "unacceptable" and measures must be taken to reduce this value. 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, acting as a safety margin to cover any unintended cumulative or cocktail effects of mixtures. The numerical value of this factor is unknown at present, however, a factor of 10 has been considered by RIVM[17]. The potential application of a MAF would mean that some current RCRs of less than 1 would be elevated to greater than or equal to 1, meaning that risks are not considered to be controlled for that substance. This essentially generates a stricter definition of what may be considered safe, when accounting for exposure to multiple substances from

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

multiple sources and the combination effects of these unintended mixtures. The aim is to reduce the risk from combined exposure to chemicals.

For this exercise, a MAF of 10 has been applied to the current RCRs of selected chemical substances as a realistic scenario, resulting in all RCRs of greater than or equal to 0.1 demonstrating an unacceptable risk once the MAF has been introduced. This exercise details the potential options available to registrants to reduce all RCRs below 1 when a MAF of 10 was applied (i.e., below 0.1 before the MAF is introduced). The work forms the basis of a consultation with chemical companies to ascertain the economic impacts that the introduction of a MAF would have. The case study forms part of a larger assessment performed by Ricardo for Cefic.

3 Methodology overview

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 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 businesses, that is, REACH registrants, could be affected. The potential knock-on implications on the chemicals industry associated with the selected registrations and the broader economy were also characterised to the extent possible, more qualitatively.

Where possible, the methodology was inspired or based on the European Commission Better Regulation Guidelines and Toolbox, although this is a focussed 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.

Once the substances were selected to represent low, medium and/or high business impacts from the revision of existing assessments, the methodology comprises the following six steps:

- **Step 1: Technical review of Chemical Safety Reports** (CSRs). The four selected substances cover low, medium, and high potential human health and environmental impacts, thus representing the breadth of potential impacts on the EU chemicals industry. The implications of applying a MAF of 10 to the RCRs of each CSR were investigated. Experts 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 RCRs below 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[18]. 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 focussed on the chemicals 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: Stakeholder consultation and evidence gathering.** Registrants of the four selected substances were engaged as part of this project. This was a central and horizontal task that provided the evidence required to progress with the development of the case studies of potential impact of the application of a MAF of 10. The consultation activities and data

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

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 Better Regulation Toolbox. These activities included a targeted consultation online survey, targeting members of the Consortia for each of the selected substances. The online survey followed a similar approach to a recent Study by Ricardo for Cefic[19], further detailed in Annex I. Interviews with a range of the survey respondents were also carried out to test and challenge their responses and ensure they would be interpreted effectively. The consultation activities were complemented by a rapid literature review.

- **Step 4: Define and characterise the baseline scenario against which to assess the MAF.** The study considered how the EU-27 market of the selected substances would likely evolve without any further policy changes in the EU chemicals legislation. This work was inspired by the European Commission's Better Regulation Guidelines, and particularly drawing from Tool #60 (Baselines). This step could only be taken for the 2 substances for which sufficient data was obtained.
- **Step 5: Assess the business and economic impacts of the policy options.** Business and economic impacts were assessed for two substances for which sufficient evidence was collected as part of the stakeholder consultation activities (one representing potentially higher impact on human health and one lower impact on human health and the environment). The quantitative analysis was based on the 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 interviews. This step could only be taken for the 2 substances for which sufficient data was obtained.
- **Step 6: Conclusions**. The quantitative and qualitative evidence on business and economic impacts for the two cases was employed to present the implications of a MAF of 10. These implications have also provided a basis to develop insights and/or conclusions for consideration by policymakers as they continue to develop the options and ambitions set out within the CSS. Due to the consultation being limited to registrants of the substances (substance manufacturers or importers), supply chain effects have not been quantified in detail and may present a larger economic impact than is provided in this report.

[19] 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 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. To note, the actions identified through the technical review of the CSRs are indicative and based on the evidence that was available from the CSRs provided. The refinement options may need to be adjusted depending on the site and data generation may not provide the desired result.

4.1 Chemical Safety Reports

CSRs resulting from Chemical Safety Assessments (CSAs) for six substances were provided by members of Cefic, with agreement from their Consortia. Tonnage information, exposure scenarios, uses, hazard values, exposure assessments and resulting RCRs presented in the CSRs were investigated for the six substances to select those that would represent a range of potential business impacts (low, medium and high). 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, impacted exposure routes and magnitude, tools used per route, use of estimated/ measured parameters for assessment, the impacted life cycle tree component (e.g., formulation, consumer uses) and possible hazard refinements (e.g., toxicokinetics (TK), 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 (Table 4-1). All substances had quantitative risk characterisations for their respective human health and/or environmental assessments, and were therefore considered in scope for the MAF. Where possible the same substances were selected for both human health and the environment, but there was a disparity between the severity of the impacts for human health and the environment, e.g., substance 4 was selected to be used in the human health evaluation, but no environmental RCRs of equal to or greater than 0.1 existed for this substance, so it was excluded from the environmental evaluation.

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

	Environment	Human Health
Substance 1	L	M
Substance 2	M	L
Substance 3	H	N/A
Substance 4	N/A	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, these actions are:

- A. Adjust values for Risk Characterisation Ratios without substantially changing the exposure assessment.
- 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.).[20]

For the environment, Option A was only an option for uses where RCRs would not be affected (i.e., where they do not exceed 1) by the introduction of a MAF of 10, while the others were considered in turn for impacted uses. For human health, Option A was applied for all uses irrespective of the affected RCR. 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 limiting the use of the substance could be achieved via a reduction in actual tonnage or concentration of the substance to achieve the outcome that risks are considered controlled. However, the boundary between each of these options map overlap 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 options D and/or E as the other potential options were not considered realistic or feasible by the registrants.

4.2 Environment

The substance selected as being "low" impact (substance 1) following the introduction of a MAF of 10 was allocated primarily due to the low number of RCRs greater than or equal to 0.1, and because all six impacted RCRs were from the same environmental compartment (sewage treatment plant (STP)). The substance deemed likely to incur a medium level of impacts (substance 2) had a higher proportion of uses impacted and included aquatic as well as terrestrial affected RCRs. The "high" impact substance (substance 3) had an even higher proportion of impacted uses, and also included man via the environment RCRs.

4.2.1 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 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), a number of options were available under action B. Firstly, it seemed feasible to ask companies whether the site tonnage assigned to each use was realistic or whether it could be reduced, as the local site tonnage made up a large proportion of the total registered tonnage in some cases and the total registered tonnage was being double-counted across multiple uses. Reducing the site tonnage used each day can be achieved by either refining the annual tonnage, or increasing the number of emission days, whichever is deemed most feasible by the company. A second potential option was identified for the formulation use, whereby the

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

approach used to estimate the water emission factor could be changed from a generic value to FEICA / EFCC SPERC 2.1b.v3, reducing the water emission factor to 0%. For the other uses, site specific release estimates from production processes for water were already in place and therefore using a SpERC would be unlikely to improve estimates.

For substance 2 ("medium" impact) no options under B were presented. The assessment was company specific, thus site tonnages could not be reduced without reducing real tonnages, and specific release fractions or appropriate SpERCs were already in place.

For substance 3 ("high" impact), the assessment was not company specific and therefore it was suggested that companies may be able to reduce the assumed largest site tonnage. For most of the uses this reduction would have to be achieved by refining the annual tonnage, however, for industrial use in coatings, increasing the emission days would also sufficiently reduce the RCR, with no reduction in annual tonnage. The air and water emission estimates relevant to the affected aquatic and man via environment RCRs were already specific enough and unlikely to be improved further.

4.2.2 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. the no-observed effect concentration (NOEC) or concentration that causes an effect in 10% of the test organisms (EC_{10})) by an assessment factor. Thus, increasing the PNEC can 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. 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[21]. It was also considered whether substance property data 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 increasing the STP PNEC could potentially be achieved by repeating the existing test with a higher test concentration range. The test currently forming the basis of the PNEC used a maximum test concentration of 100 mg/L, with the EC_{10} value expressed as greater than this (>100 mg/L). It should be noted that there was no guarantee that this new test would generate a lower $EC_{10,}$ as toxic effects may be observed at the higher concentration. For industrial use as a monomer (2) and as an intermediate (2), site-specific exposure measurements were also deemed feasible, provided this would lead to emission estimates to waste water being reduced by at least a factor of two.

A similar set of options were presented for substance 2. For the aquatic RCRs of every impacted use, emission to waste water could potentially be reduced through site-specific measurements, and generation of toxicity test data could increase the sediment and soil PNECs which were previously estimated based on EPM. The soil RCRs were driven by air emissions (i.e. via aerial deposition) rather than water emissions, so it is possible that measurement would improve the air emission fraction.

Substance 3 required either one or multiple options to fix all the RCRs, depending on the use: a) Reducing the emission to waste water through site-specific measurements, b) Refining the oral PNEC,

[21] 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

and c) For uses with an impacted man via environment RCR, reducing the emission to air through generic volatile organic compound (VOC) measurements at site.

4.2.3 Action D

Most exposure scenarios assume the implementation and use of risk management measures (RMMs) to control the amount of substance released in waste water, 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).

No suitable RMMs were found for substance 1, and only the use of additional air RMMs (such as wet scrubber) was appropriate for the use of substance 2 in coatings. RMMs for substance 3 included a number of water RMMs (stripping, nanofiltration, distillation, or oxidation) and air RMMs (such as dry and wet scrubbing, condensation, or bio-trickling) for manufacturing and formulation uses, as well as improving the efficiency of existing air RMMs to ≥99%. For all other uses, only stripping was identified as a suitable water RMM, and no air RMMs needed to be used.

The application of 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. However, stopping this application was not a necessary option for any of the substances. No soil RCRs were affected for substance 1 and there was no assumed sludge to soil application for substance 3. While the soil RCR was affected for substance 2, this was driven by air emissions, not sludge application.

4.2.4 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 steps A-C. For each substance the maximum site tonnage per day that would be needed to fix each RCR (i.e. calculated for each environmental compartment for every impacted use) was calculated. 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 required for all the RCRs for each use to remain below 0.1 ranged from 33.3% (formulation) to 90% (manufacturing, industrial uses) for substance 1, from 34% (formulation) to 74% (industrial use as an intermediate) for substance 2, and from 56% (industrial use in coatings) to 89% (manufacturing, formulation, industrial use as an intermediate, industrial polymer production and rubber production and processing) for substance 3. 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.

4.3 Human Health

The substance selected as being “low” impact (substance 2) following the introduction of a MAF of 10 was allocated primarily due to a single route of exposure (only inhalation) and had scope for refinement. The substance deemed likely to incur a medium level of impact (substance 1) had exposures via both inhalation and dermal routes, and also had scope for refinement on both hazard and exposure aspects. The “high” impact substance (substance 4) was considered to have an even higher business impact as an occupational exposure limit (OEL) and “measured values” had already been implemented.

Each substance-specific CSR/assessment tool file was reviewed and converted into an Excel format to conduct the assessment with a MAF of 10 (including the scenario name, identifier, routes, long- versus short-term exposure, systemic versus local effect, tools versus measured).

Under the scope of the current MAF assessment, the substances were reviewed to determine the different theoretical actions under options A, B, C and D, which could be explored before proceeding to Option E. Some of the actions under options 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 options B and C (exposure) and D were PROC/PC/AC specific. However, the feasibility of implementing these theoretical possibilities, which were aimed to reflect realistic use conditions, would require 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 substances was considered to be appropriate and there was no further scope for refinement under Action A. In terms of impacted uses following application of MAF of 10, substance 1 had 95% and 43% of the uses impacted for inhalation and dermal routes respectively, while substances 2 and 4, which only had one relevant route of exposure via the inhalation route, had 100% and 74% of their uses impacted 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 tools. These options were not mathematically “tried” and therefore were considered as “potential refinement” actions requiring final validation and assessment by the registrants during the economic assessment.

For substance 1 (medium impact) and substance 2 (low impact), no refinement possibilities could be identified for the hazard assessment parameters. However, there was a scope for refinement by modifying the exposure parameters (e.g., duration of activity, vapour pressure at elevated temperature, implementation of industry associations SWEDs/SCEDs) and using higher tier tools with more realistic conditions of use.

For substance 4 (high impact), no refinement possibilities could be identified for the hazard assessment parameters or by implementation of industry associations SWEDs or use of higher tier exposure tools. There was some possibility for refinement of the exposure parameters (e.g., duration of activity), however, the feasibility of implementing the theoretical options needed 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, the 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 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 will have a relatively higher economic impact compared to the actions explored under options 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.

For substance 1 (medium impact), the generation of dermal absorption study or higher tier tox studies (if available in future) may help 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) as the DNEL is based on IOEL, there was very little, if any, scope for refinement. Availability of a higher tier reproductive toxicity study in the future is also not likely to influence the DNELs. For both substance 1 and 2, although generation of biomonitoring data has not been recommended at this stage, its applicability may be explored in the future which could lead to higher economic impact.

For substance 4 (high impact), toxicokinetic and higher tier toxicological studies were already available, and the substance has a harmonised classification; with the DNEL being based on OEL value derived from a chronic study. Also, the exposure assessment was based on biomonitoring data. Therefore, implementation of any of the proposed actions from Option B or D (e.g., new RMMs/Personal Protective Equipment) for the exposure scenarios would need the regeneration of biomonitoring data leading to high economic impact.

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, i.e. whether the suggested RMMs are feasible based on the substance properties and exposure route.

For substances 1 and 2, a possibility of refining the Tier 1 RMMs/PPEs (e.g., respiratory protection, room ventilation) and/or higher RMMs/PPEs (e.g., drum pump or engineering controls or containment) were suggested.

For substance 4, only a possibility of refining some of the RMMs/PPEs reflecting the feasible options under the real conditions of use (e.g., respiratory protection, local exhaust ventilation) were suggested, which would then require re-generation of biomonitoring data.

4.3.5 Action E

This is the final type of action defined by the ECHA methodology, which involves modifying the percentage of substance in preparation[22], 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.

All three evaluated substances had potential for refinement by reducing the percentage of substance in preparation for some of their PROCs.

However, for some substances, the reduction of the percentage of a substance may not be a realistic or 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., 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. All these restrictive actions, however, required review and confirmation by the registrants during the economic assessment.

The proposed actions under the current scope of MAF assessment are theoretical possibilities or examples, which were based on the review of the available information and a limited understanding of

[22] Corresponding to reducing the concentration of the substance in the final product

the described conditions of uses. A more realistic assessment along with the feasibility analysis of the proposed options for action has been delegated to the registrants.

4.4 Outcomes of Technical Analysis

Table 4-2 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	**Uses impacted (%)[23]**	**Refinement options**	**Impact**	**Refinement options**
1	• Inhalation route: 95% • Dermal route: 43% • Oral route: Not relevant (no oral exposure expected) • Combined routes: 95%	**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 industry associations SWEDs/SCEDs, • implement or modify higher tier tools assessments. **C** (generate data): • Some scope for refinement – Dermal absorption study, higher tier tox studies (if available in future) may help refining DNELs; • Biomonitoring not recommended at this stage; maybe explored in future **D** (additional RMMs): • Potential refinement on Tier 1 RMMs/PPEs (e.g. respiratory protection, room ventilation)	• Manufacturing and five industrial uses • STP RCRs	**B** • Reduce assumed site tonnage by up to factor 10 • Possible alternative SpERC for formulation use **C** • Additional testing to refine PNEC (repeat limi+t test at higher concentration) **E** • Reduce actual site tonnage by up to factor 10

[23] Percentage of uses which will be impacted by the MAF due to impact on human health for the substance. e.g. 95% of uses will be deemed unsafe for exposure via the inhalation route following the application of the MAF without refinement.

Substance	Human Health		Environment	
	Uses impacted (%)[23]	Refinement options	Impact	Refinement options
		and/or higher RMMs/PPEs (e.g. drum pump) **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.)): • Limit percentage of substance in preparation. Combinations of B and D refinements could be considered		
2	• Inhalation route: 100% • Dermal route: Not relevant (qualitative assessment) • Oral route: Not relevant (no oral exposure expected) • Combined routes: 100%	**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, vapour pressure at elevated temperature), • implement industry associations SWEDs, • implement higher tier tools assessment **C** (generate data): • Not much scope for refinement – DNEL based on IOEL; higher tier	• Formulation and two industrial uses • Aquatic, STP and soil RCRs	**C** • Site-specific measurements of water and air emissions • Refine sediment and soil PNECs through additional testing (currently EqP approach) **D** • Additional air RMMs for one industrial (downstream) use **E** • Reduce site tonnage (up to 65% reduction)

Substance	Human Health		Environment	
	Uses impacted (%)[23]	Refinement options	Impact	Refinement options
		reproductive toxicity study although not available, it is not likely to influence the DNELs; • Biomonitoring not recommended at this stage; maybe explored in future **D** (additional RMMs): • Potential refinement on Tier 1 RMMs/PPEs (e.g. respiratory protection, room ventilation) and/or Higher RMMs/PPEs (e.g. engineering controls or containment) **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.)): • Limit percentage of substance in preparation		
3			• Manufacturing and six industrial uses • Secondary poisoning and man via environment RCRs	**B** • Reduce assumed site tonnage by up to factor 10 **C**

Substance	Human Health		Environment	
	Uses impacted (%)[23]	Refinement options	Impact	Refinement options
				• Site-specific measurements of water and air emissions • Refine user-defined PNECoral (UVCB substance) **D** • Additional water and air RMMs **E** • Reduce actual site tonnage by up to factor 10
4	• Inhalation route: 74% • Dermal route: Not relevant (no DNEL) • Oral route: Not relevant (no DNEL • Combined routes: 74%	**A** (adjust RCR values without substantial modifications): • Baseline data appropriate; no scope **B** (revise based on existing data): • Refine exposure parameters related to measured values conditions (e.g., duration of activity **C** (generate data): • Not much scope for refinement – Substance has harmonised classification;		

Substance	Human Health		Environment	
	Uses impacted (%)[23]	Refinement options	Impact	Refinement options
		• TK and higher tier tox studies already available; DNEL based on OEL; • Original exposure assessment based on biomonitoring data; • potential refinements suggested in B and D maybe implemented and a new biomonitoring study maybe considered **D** (additional RMMs): • Potential RMMs/PPEs refinements in real conditions of use (e.g. Respiratory protection, LEV **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.)): • Limit percentage of substance in preparation		

5 Case Studies – Business impacts

Based on the evidence gathered, this section describes the analysis of the baseline for a number of chemical businesses registering substances 2 and 4; the likely response from these businesses if a MAF of 10 were introduced; and the resulting potential impact on these businesses. Five core economic indicators were employed as a proxy for the business and knock-on economic implications, as highlighted in Section 3, including turnover, Gross Value Added (GVA), capital expenditure, operating expenditure and the number of jobs supported.

5.1 The baseline

Businesses registering the selected four substances were consulted and a sample of four or more respondents were secured for two of these substances.

A group of registrants of substance 2 have placed 0.2-1.2 million tonnes of their substance on the market, generating 140-320 million euros in turnover in 2019. This may have contributed around 60 million euros in GVA to the EU-27 economy. For the respondents, the primary points of use of the substance in the supply chain are formulation and (re)packaging, manufacturing, and use at industrial sites. The substance is predominantly used as an intermediate in chemical production and in consumer products that include household products.

Without the introduction of the MAF, substance registrants estimate that their turnover could grow between 0.5%-1.5% annually, on average, over the coming decades. These businesses employ a total of 500 to 1,000 people (full-time equivalent), which would be estimated to increase by 0.2%-0.6% per year, on average, over the timeline. These businesses also purchase goods and services from other businesses in the EU-27 and internationally, worth hundreds of millions of euros each year. These registrants make a considerable economic contribution.

A group of registrants of substance 4 placed between 1-3 million tonnes on the market, generating between 2.3-4.5 billion euros in turnover, and contributing around 900 million euros in GVA to the EU-27 economy. The primary point of use of the substance in the supply chain are use at industrial sites, in formulation and (re)packaging, manufacturing and professional uses. Substance 4 also has consumer uses, albeit to a much lesser extent. The sales value of a key product derived from this substance is also estimated to hold a market value of hundreds of billions and is a relevant input to industries such as the automotive, construction, and consumer appliances sectors.

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

5.2 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 selected substances may have to respond to the introduction of a MAF of 10, employing a framework developed by ECHA.

Registrants for substance 2 identified a range of type A-E actions that, if taken, could result in an RCR below 1 for the substance, in the context of a MAF of 10 (i.e., risks are considered “controlled” in this new regulatory context, when accounting for exposure to multiple substances from multiple sources and the combination effects of these unintended mixtures). Overall, the most relevant include:

- Updating risk assessments for revised exposure scenarios, including based on potential introduction of risk management measures downstream. These downstream measures include filters to reduce air emissions, engineering measures to remove VOC emissions, reducing concentration and local exhaust ventilation.
- Revising exposure scenarios using higher tier tools.
- Generating data through measurements of emissions to waste water and/or air to review assessment factors.
- Introducing new risk management measures, such as improving ventilation during loading and unloading for workers.
- Withdrawal of the substance (1%-20% on average), exacerbated by pressures from reductions in purchases by downstream users and despite some opportunities to substitute and/or introduce alternatives into the market (1%-50% of the market value of the substance depending on the use).

Registrants of substance 2 were able to identify their potential business response; however, there is uncertainty of the potential cost implications of MAF on downstream users. The registrants identified that downstream users would bear the majority of the costs as they would be required to implement substantial risk management measures. With increasing costs to mitigate the MAF and a limited number of readily available alternatives and substitutes with similar functionality, it is considered that final products that need substance 2 in their formulation would need to be increasingly manufactured abroad and imported into the EU.

Registrants for substance 4 were not able to identify any type A-C actions that, if taken, could support the uses of the substance in a context of a MAF of 10. For example, the exposure scenarios are already refined and based on actual data, thus no more action can be taken to further improve these.

The registrants identified Type D-E actions that they may need to take in the context of a MAF of 10. In general, these include:

- Introducing new risk management measures, such as investing in closed processing and automation of sampling and other operation activities, in a way that would reduce the exposure to workers during the manufacturing and reformulation of the substance (and thus the RCRs) across the primary uses of the substance.
- Withdrawal of the substance from some uses without any substitution (10%-80% net withdrawal on average), as no alternative substances with lower RCRs that fulfil the same purpose have been found (in fact, any other options would likely have detrimental impacts on human health due to more severe hazard profiles and result in lower product performance).

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 (by 10% or more on average). This is considered in the following sections.

There is significant uncertainty. Some registrants have also identified that there could be a need to move parts, or all of their manufacturing and other business activity related to the substance outside of the EU-27, although the decision to do this would be based on a number of factors. In this scenario, the introduction of the MAF would be potentially pushing business activities (and any associated manufacturing risks) to third countries, with the EU increasing the import of finished products (e.g., cars, refrigerators, construction elements, etc.).

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

Table 5-1 Impact scenarios and uncertainties

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

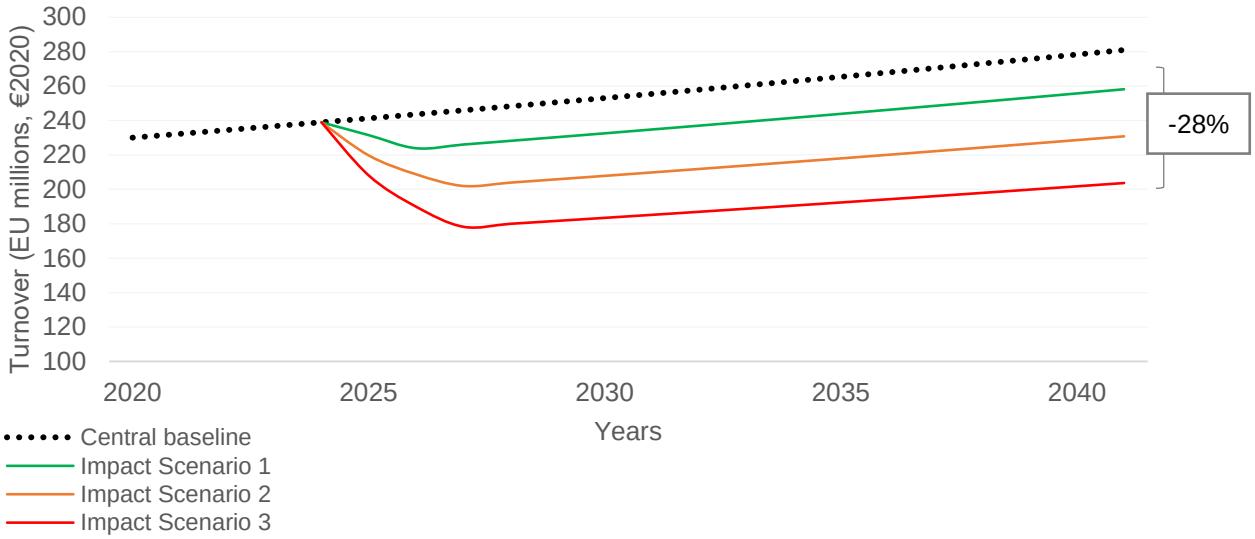
5.3 Impact on chemicals businesses in the EU-27 and knock-on economic implications

Based on the evidence collected and analysis of potential business responses against the baseline, a team of economists considered how the key business and economic indicators may be affected over the next decades.

5.3.1 Substance 2

The annual sales value for substance 2 is estimated to be between 23-77 million euros lower in 2040, with a central estimate of around 50 million euros (or 18%) lower when compared against the central baseline scenario. The analysis carried out for this Study suggest that turnover losses in 2040 would likely range from 8% to 28%, when compared to the baseline. There is uncertainty with regards to the downstream user response and the associated costs. Businesses downstream would also face regulatory and cost pressures and, as a result, are estimated to reduce their demand of the products. This is shown in Figure 5-1 below.

Figure 5-1 Substance 2 –Estimated impact of MAF on the turnover of registrants (or estimated turnover losses against the central baseline)*



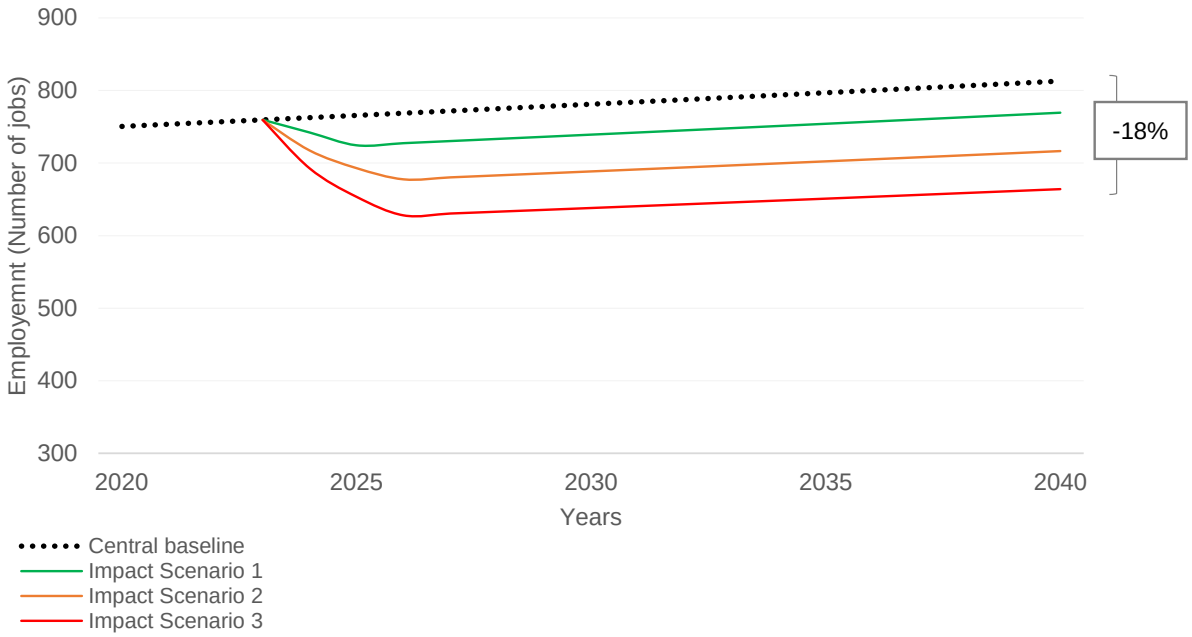
*Please note the figure is presented with a truncated axis to be able to see differences between the scenarios, it is not the intent to suggest that the impacts are more or less significant than they are described quantitatively.

Considering additional uncertainties with regards to the baseline projections, market losses in the EU-27 could range between 13 million euros (in the low impact scenario 1) to 120 million euros (in the high impact scenario 3) against their respective baselines in 2040.

These implications on the substance's market, especially in the central (2) and high impact scenarios (3), could **disrupt the European supply chain for substance 2**, and would affect industries such as the consumer products, coatings, cleaning and construction sectors. Albeit alternative substances are available, substitution remains a challenge. For example, there is a lack of suitable substitutes for substance 2 that offer similar benefits in coating and cleaning applications. When considering the knock-on effects, the economic implications would therefore be significantly higher.

Employment in the EU-27 associated with the manufacture and use of substance 2 by its registrants is estimated to decrease marginally when compared to the baseline. Figure 5-2 below shows the low, central and high impacts compared to the central baseline only. By 2040, central estimates suggest that substance registrants may be faced with the challenge of cutting jobs in the EU-27 by around 12%, with job losses ranging from 5-18% when compared to the baseline.

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



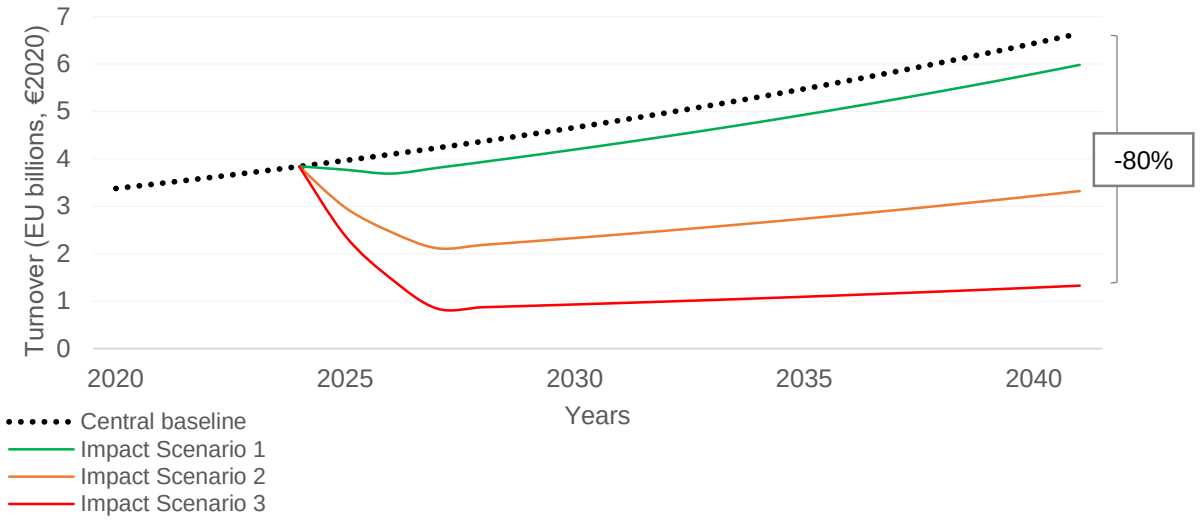
*Please note the figure is presented with a truncated axis to be able to see differences between the scenarios, it is not the intent to suggest that the impacts are more or less significant than they are described quantitatively.

These emerging results also illustrate a negative, direct impact on the sector's contribution to EU-27 GDP by 2040. The direct contribution to GDP of registrants would be between 5-20 million euros lower than the baseline. They also **capture a negative impact on the global competitiveness** of the substance manufacturers in the EU-27. Further, **imports of the substance and its mixtures could experience a slight rise** to meet demand that can no longer be serviced by EU manufacturers, where there is sufficient capacity to manufacture substance 2, or suitable alternatives, outside of the EU.

5.3.2 Substance 4

It is estimated that the annual sales value of the EU-27 manufacturing of substance 4 would be reduced by between 660 million to 5 billion euros in 2040, with a central estimate of 3 billion euros in turnover losses (or 50% lower) when compared to the baseline scenario. There is significant uncertainty with regards to the business responses, which is captured in Figure 5-3 below. Whereas some businesses have identified risk management measures that could allow for the continuation of manufacturing and use of the substance, others have not. More importantly, businesses downstream would also face regulatory pressures and, as a result, they are estimated to reduce their demand – additional downward pressure on the substance's market.

Figure 5-3 Substance 4 – Estimated impact of MAF on the turnover of registrants (or estimated turnover losses against the central baseline)

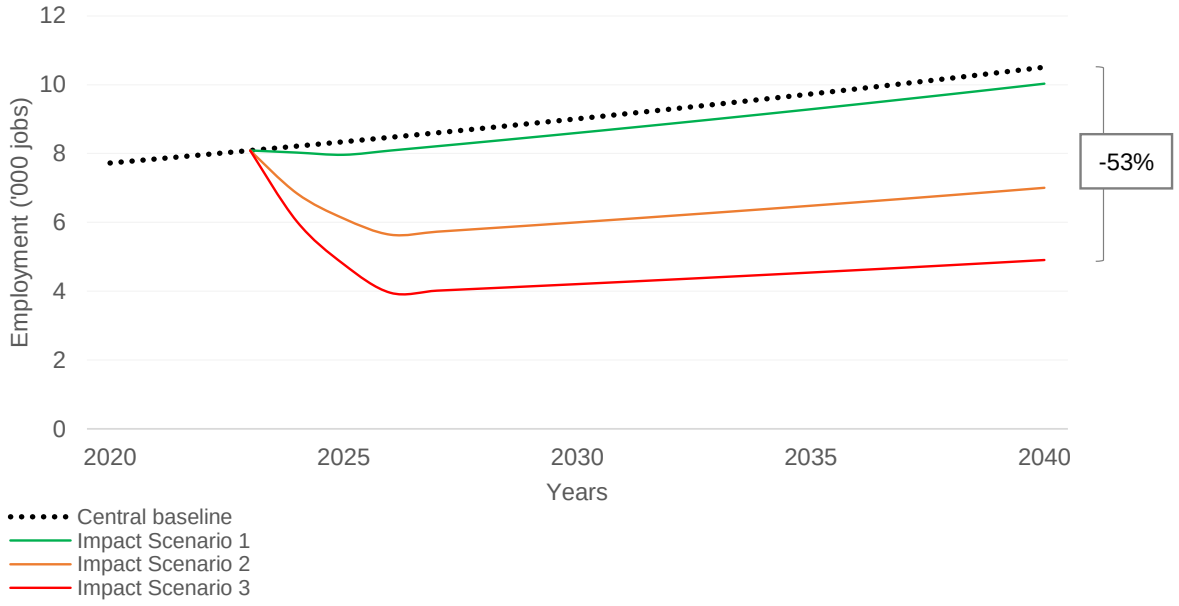


When considering additional uncertainties associated with the baseline projections, market losses in the EU-27 could range between 350 million euros (in a low impact scenario 1) to 9 billion euros (in the high impact scenario 3) against their respective baselines (a broader range than what is depicted in Figure 5-3 above).

These impacts on the substance's market could **disrupt the European supply chain for a product that is worth hundreds of billions of euros**, and would affect industries requiring this product, such as the automotive, construction and consumer appliances sector. Therefore, the broader economic implications could be significantly higher.

Employment in the EU-27 manufacturing of substance 4 is also estimated to be negatively affected when compared to the baseline, albeit with lower intensity than turnover. Direct losses could reach up to 5,600 FTE jobs (or 53% lower) in the EU-27 by 2040, with central estimates suggesting 3,500 jobs would be lost (or 33% lower) when compared to the baseline. This is shown in Figure 5-4 below, capturing the uncertainty in the likely business response to the introduction of MAF.

Figure 5-4 Substance 4 - Estimated impact of MAF on the employment supported by the registrants (or estimated loss of employment against the central baseline)



When considering additional uncertainties associated with the baseline projections, substance registrants may be faced with the tough decision to cut direct jobs in the EU-27 by between 300 and 8,700 FTE against their respective low and high baselines.

In the lower impact scenario (or Impact Scenario 1), registrants also estimate to substantial capital investments, in the scale of billions of euros over the period. This would be primarily focussed on adjusting their operations and introducing risk management measures so the risks from their manufacturing and use of the substance remains controlled when the MAF of 10 is applied.

These emerging results illustrate a negative, direct impact on the sector's contribution to EU-27 GDP by 2040. The direct contribution to GDP of registrants would be between 0.2 and 1.4 billion euros lower than the baseline. They also **capture a very negative impact on the global competitiveness** of the substance manufacturers in the EU-27. Further, **imports of the substance and its mixtures could rise significantly** (10% or more on average) to meet demand that can no longer be serviced by EU manufacturers, although there is uncertainty around the international capacity to address these needs. Importing more final products associated with substance 4 may face difficulties with the lack of availability of substance 4 outside the EU, logistical challenges and the time lag for international supply chains to meet the potentially unmet needs in the EU.

The impacts on turnover and employment across all scenarios remain significant for substance 2 albeit less so than for substance 4. Registrants of substance 2 are able to take actions that can address the regulatory requirements of a MAF of 10 whilst mitigating some of the business effects. With the existing chemical regulations on substance 4 and lack of substances with lower RCR that fulfil the same functionality, any further measures to reduce exposure are estimated to be very costly and with uncertain success. Therefore, the withdrawal of business activity in the EU-27 is considered to be more likely and at a higher scale than is estimated for substance 2.

6 Conclusions

A targeted online consultation, interviews with registrants of two different chemical substances and a rapid economic analysis revealed that the introduction of a MAF of 10 could have substantial implications on the chemicals 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 two different chemical substances or case studies. Through a technical assessment, a range of possible actions for registrants of substances 2 and 4 were identified that could keep their RCRs below 1 in a context of MAF of 10 (i.e., risks are considered "controlled" 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. The conclusions are outlined in Table 6-1.

Table 6-1 Potential business responses by Case Study Substance

Case studies	Potential business responses to a MAF of 10
Substance 2	The registrants consulted would generally **continue manufacturing the substance in the EU-27, whilst also taking the following action:** • Updating risk assessments • Revising exposure scenario • Generating emission data • Introducing further risk management measures to reduce worker/professional exposure • Withdrawal of the substance as clients reduce their purchases of the product
Substance 4	The registrants consulted would generally **continue manufacturing and using the substance in the EU-27, whilst they would take significant action:** • Introduce further risk management measures to reduce worker/ professional exposure • Withdraw products from the market

The adoption of a MAF of 10 and the resulting business actions would have implications on the chemicals market and associated supply chains. In particular, the market for substance 2 is also estimated to suffer turnover losses, with a central estimate of around 50 million euros (or 18%) when compared against the central baseline scenario. The market for substance 4 is likely to be significantly affected, with a central estimate of 3 billion euros (or 50%) 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 billions of euros in value added.

Further, the effects on the chemicals industry would also result in potential losses of thousands of jobs in the EU-27, a worsening of the competitiveness of the EU-27 industry, and a shift towards increasing imports of final products, increasing the dependency on third countries for chemical substances and/or products previously manufactured and used in supply chains across the EU. As a result, supply chains worth hundreds of billions would be affected and potentially disrupted, which would have additional negative economic implications across the EU.

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 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 and one-to-one interviews with registrants of the substances, 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.

Over 40 registrants of the four selected substances were contacted, albeit sufficient responses were provided for two of these only. Therefore, the analysis of data and development of case studies focussed on substances 2 and 4.

The targeted stakeholder online survey sought was designed to elicit evidence and informed views from businesses in four parts and 55 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 each substance 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 one-to-one interviews with registrants were undertaken to challenge 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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