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IMPACT ASSESSMENT

Accompanying the document

Proposal for a Directive of the European Parliament and of the Council

amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

{COM(2020) 571 final} - {SEC(2020) 302 final} - {SWD(2020) 184 final}

Table of contents

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT ... 1
2. PROBLEM DEFINITION ... 5
2.1. What is/are the problems? ... 5
2.2. What are the problem drivers? ... 6
2.3. How will the problem evolve? ... 11
3. WHY SHOULD THE EU ACT? ... 12
3.1. Legal basis ... 12
3.2. Subsidiarity: Necessity and added value of EU action ... 13
4. OBJECTIVES: WHAT IS TO BE ACHIEVED? ... 15
4.1. General objectives ... 15
4.2. Specific objectives ... 15
4.3. Consistency with other EU policies ... 15
5. WHAT ARE THE AVAILABLE POLICY OPTIONS? ... 17
5.1. Process for setting binding OELs and associated provisions under CMD ... 17
5.2. Description of the retained policy options for establishing binding OELs under the CMD ... 17
6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS? ... 19
6.1. Acrylonitrile ... 20
6.2. Nickel compounds ... 24
6.3. Benzene ... 30
7. HOW DO THE OPTIONS COMPARE? ... 35
8. PREFERRED OPTIONS ... 38
8.1. Summary of the preferred options ... 38
8.2. Overall impact of the package or preferred options ... 39
9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED? ... 45
9.1. Monitoring arrangements ... 45
9.2. Evaluation arrangements ... 47

ANNEX 1: PROCEDURAL INFORMATION ... 48
ANNEX 2: STAKEHOLDER CONSULTATION ... 53
ANNEX 3: WHO IS AFFECTED AND HOW? ... 63
ANNEX 4: ANALYTICAL METHODS ... 70
ANNEX 5: NATIONAL OELS ... 96
ANNEX 6: RELEVANT SECTORS, USES AND ACTIVITIES ... 110
ANNEX 7: ROUTE(S) OF EXPOSURE, ADVERSE HEALTH EFFECTS ... 153
ANNEX 8 – PROCESS FOR SETTING BINDING OELS AND ASSOCIATED PROVISIONS UNDER THE CMD ... 156
ANNEX 9 – OPTIONS DISCARDED AT AN EARLY STAGE ... 160
ANNEX 10 – CONSISTENCY AND SYNERGIES WITH THE REACH REGULATION ... 163

Disclaimer. *Unless otherwise specified, the information and views set out is this report refer to EU28 aggregated data collected before the 1st February 2020, date of the withdrawal of UK from the EU.*

Glossary

Term or acronym	*Meaning or definition*
ABS	Acrylonitrile-Butadiene-Styrene
ACSH	Advisory Committee on Safety and Health at Work
ASA	Finnish Register of Workers Exposed to Carcinogens (altistuminen syöpäsairauden vaaraa aiheuttaville tekijöille (ASA-luettelo))
BLV	Biological Limit Value
CAD	Chemical Agents Directive (Directive 98/24/EC)
CAREX	CARcinogen EXposure database
CDB	Current Disease Burden
CEEMET	Council of European Employers of the Metal, Engineering and Technology-based industries
CEFIC	European Chemical Industry Council
CESI	European Confederation of Independent Trade Unions
CLP	Classification, Labelling and Packaging Regulation (Regulation (EC) No 1272/2008)
CMD	Carcinogens and Mutagens Directive (Directive 2004/37/EC)
COPD	Chronic Obstructive Pulmonary Disease
COWI SA	Consulting Group
CSRs	Chemical Safety Reports
DALY	Disability-Adjusted Life Year
DEEE	Diesel Engine Exhaust Emission
DNEL	Derived No Effect Level
DRR	Dose Response Relationships
ECEG	European Chemical Employers Group
ECHA	European Chemicals Agency
EFBWW	European Federation of Building and Woodworkers
EODS	European Occupational Diseases Statistics
EPSU	European Public Service Union
ERR	Exposure Risk Relationship
ETUC	European Trade Union Confederation
EU-OSHA	European Agency for Safety and Health at Work
FDB	Future Disease Burden
GDP	Gross Domestic Product

GDV	General Dilution Ventilation
IARC	International Agency for Research on Cancer
INRS	Institut National de Recherche et Sécurité
IMF	International Monetary Fund
Lat	Latency
LEV	Local Exhaust Ventilation
MaxEx	Maximum Exposure
MinEx	Minimum Exposure
MoR	Mortality Rate
NACE	Nomenclature des Activités Économiques dans la Communauté Européenne
NHS	UK’s National Health Service
OEL	Occupational Exposure Limit (value)
OSH	Occupational Safety and Health
PPE	Personal Protective Equipment
PROCs	United Kingdom’s National Health Service
PV	Present Value
R&D	Research and Development
RAC	Risk Assessment Committee of ECHA
REFIT	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
RMMs	Risk Management Measures
RMOA	Regulatory Management Option Analysis
RPE	Respiratory Protective Equipment
SAN	Styrene-Acrylonitrile
SDS	Safety Data Sheet
SLA	Service Level Agreement
SLIC	Senior Labour Inspectors' Committee
STEL	Short Term Exposure Limit
SVHC	Substance of Very High Concern
SWD	Staff Working Document
TFEU	Treaty on the Functioning of the EU
TWA	Time-Weighted Average

UEAPME	European Association of Craft Small and Medium-sized Enterprises
WTP	Willingness to Pay

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Cancer, irrespective of whether it is related to work or not, is the second leading cause of mortality in the EU countries after cardiovascular diseases, accounting for about a quarter of all deaths[1]. It is recognised as one of the major contributors to premature deaths in the European Union. It has an impact not only on individual health, family life, but also on the national health and social systems, the governmental budgets and the productivity and growth of the economy.

Stepping up the fight against cancer is therefore an urgent priority for the EU. To that end, as announced by European Commission President von der Leyen in her Political Guidelines[2], the Commission will present before the end of 2020, a European plan to reduce the suffering caused by the disease and support Member States to improve cancer control and care in order to ensure more fair access to treatment across the EU.

Fighting against occupational cancer is all the more necessary that occupational cancer remains the first cause of work-related deaths in the EU[3], as shown in the figure 1 below. 52% of annual occupational deaths in the European Union are currently attributed to cancer, compared to 24% to circulatory diseases, 22% to other diseases and 2% for injuries. Addressing occupational cancer will also be an integral part of the Europe's Beating Cancer Plan.

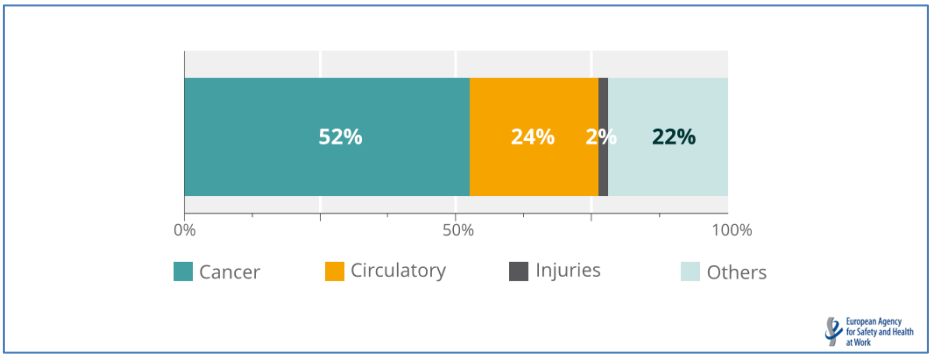

Figure 1: work-related deaths in the EU (2017)

The initiative comes in the backdrop of an unprecedented crisis for the EU and the world. The Covid-19 pandemic has major health, economic and social consequences that will need to be addressed. The pandemic also sheds light on the importance of health and safety considerations in workplaces, especially for those in the front line of the response to crisis. It gives yet another incentive to redouble the efforts to protect workers and societies from all possible occupational risks, thereby having a positive impact on employment and economy.

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[1] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Cancer_statistics#Deaths_from_cancer

[2] A Union that strives from more – My agenda for Europe, available at: https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

[3] EU-OSHA (2017), An international comparison of the cost of work-related accidents and illnesses, available at: https://osha.europa.eu/en/publications/international-comparison-cost-work-related-accidents-and-illnesses/view

A strong social Europe calls for constant improvements towards safer and healthier work for all. As outlined in the Communication on "A strong social Europe for just transitions,"[4] measures for the protection of workers need to keep up with a wide range of social, economic and technological developments while at the same ensuring continuous protection from traditional risks. In this Communication, the Commission has already committed to review the occupational safety and health (OSH) strategy to address among others the exposure to dangerous substances, with a view to maintain European's high OSH standards. The European Pillar of Social Rights[5], jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, enshrines workers' right to healthy, safe and well-adapted work environment, including protection from carcinogens. In its Communication on "Safer and Healthier Work for All,"[6] the Commission emphasizes that European Union must continue investing in occupational safety and health and has committed to step up the fight against occupational cancer through legislative proposals. The recent extension of the Roadmap on Carcinogens[7] covenant, which was signed in Helsinki on 28 November 2019, also proves that a significant number of stakeholders continue to be committed to improve the protection of workers from the exposure to carcinogenic substances.

Reducing exposure to carcinogens and mutagens at the workplace by setting EU-wide occupational exposure limit values (OELs) effectively contributes to the prevention of cancer cases and deaths, as well as other significant non-cancer health problems caused by these substances. Consequently, it improves the protection of workers by increasing the length, quality and productivity of the working lives of European workers and ensuring a similar minimum level of protection across the EU, contributes to better productivity and competitiveness of the EU, and improves the level playing field for businesses.

In order to further contribute to a better protection of workers, this Commission continues its process of updating the Carcinogens and Mutagens Directive (CMD)[8] to keep abreast with the new scientific and technical developments and to take account of its stakeholders' views. This is in line with the Directive itself, which requires that OELs must be set for all those carcinogens or mutagens for which this is possible in the light of the available information. Consistency with the REACH Regulation[9] is ensured in this respect. The finalised REFIT Occupational Safety and Health evaluation[10] as well as the conclusions of the REACH REFIT evaluation[11] have underscored and fed into this process.

Updating and reviewing the CMD has now become a continuous process

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[4] Communication from the Commission "A strong social Europe for just transitions" COM(2020) 14 final, available at: https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:52020DC0014

[5] European Pillar of Social Rights, November 2017, available at : https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf

[6] Communication from the Commission "Safer and Healthier work for All – Modernisation of the EU Occupational Safety and Health Legislation and Policy" COM(2017) 12 final, available at : https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017DC0012

[7] https://roadmaponcarcinogens.eu/about/the-roadmap/

[8] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0037

[9] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907

[10] Ex-post evaluation of the EU occupational safety and health Directives (REFIT evaluation) - SWD(2017) 10 final, available at: https://ec.europa.eu/transparency/regdoc/?fuseaction=list&coteId=10102&year=2017&number=10&version=ALL&language=en

[11] REACH REFIT evaluation (REACH Review 2017), available at: https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

Over the last few years, the Commission proposed three directives amending the CMD. These three proposals have been adopted by the European Parliament and the Council[12 13 14]. These three revisions, which addressed 26 substances, enabled among others to revise two existing OELs, introduce 22 new OELs and set a skin notation without any OELs for the remaining two.

The REFIT OSH evaluation[15] says that "*following concerns raised by different stakeholders' groups in the evaluation process and in the National Implementation Reports, the need to adopt limit values for more substances should be considered. These additional OELs should lead to a better chemical risk management in the future".* Therefore, the Commission will continue the process of updating and reviewing the CMD with the aim to propose new or revised OELs in Annex III to the CMD.

It is not realistic to set an OEL for every hazardous chemical that may be used at the workplace. Instead, it is appropriate to identify and target priority substances. This prioritisation of the substances is based on a broad consultative approach, including opinions issued by the tri-partite Advisory Committee on Safety and Health at Work (ACSH), agreement in its Working Party on Chemicals (WPC), and formal two-stage social partners' consultation (SPC).

The selection of the specific three substances or groups of substances (hereafter "substances") considered in this impact assessment, **namely acrylonitrile, nickel compounds and benzene**, folllowed the same path, including a formal two-stage consultation of the European Social Partners launched in July[16] and November 2017[17], in accordance with Article 154 of the Treaty on the Functioning of the European Union (TFEU).

It was agreed by all relevant stakeholders, taking into account factors such as the potential to cause adverse health effects, degree of evidence of such effects, as well as their severity, potency and reversibility, that these three substances are of high relevance for the protection of workers. The Commission's intention to prepare for the establishment or revision of OELs for those priority carcinogens was confirmed and encouraged by all the stakeholders.

For the specific case of benzene, although an EU OEL of 3.25 mg/m³ already exists in the CMD since 2004, the most recent scientific and technical evidence indicates that this existing EU OEL should be updated. This is in line with the recital 13 of the CMD laying down that "*limit values must be revised whenever this becomes necessary in the light of more recent scientific data*". Furthermore, the ACSH

[12] Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398

[13] Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906467330&uri=CELEX:32019L0130

[14] Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906381017&uri=CELEX:32019L0983

[15] See footnote 10

[16] Consultation Document of 26.07.2017, First phase consultation of Social Partners under Article 154 TFEU on revisions of Directive 2004/37/EC to include binding occupational exposure limit values for additional carcinogens and mutagens, C(2017) 5191 final.

[17] Consultation Document of 10.11.2017, Second phase consultation of Social Partners under Article 154 TFEU on revisions of Directive 2004/37/EC to include binding occupational exposure limit values for additional carcinogens and mutagens, C(2017) 7466 final.

strongly recommended the Commission to adopt as soon as possible a revised OEL under the CMD for benzene.

In order to carry out its impact assessement, the Commission contracted a study[18] to COWI S/A (hereafter "COWI study") in order to collect the most recent information for the three substances. According to the data arising from this study, more than 1 million EU workers are currently exposed to these hazardous substances. This impact assessment aims to assess whether there is a need to introduce new (for nickel compounds and acrylonitrile) or revised (for benzene) OEL for these substances, to address them with other legal or non-legal initiatives, or not to take any action.

Given the level of scientific and technical knowledge required to identify measures ensuring adequate protection of workers while being practically feasible for industries, the Commission bases its proposals in this area on opinions developed by the ACSH. The opinions of ACSH take into account the scientific basis, which is indispensable to underpin OSH legislation. In order to establish this scientific basis for the ACSH, the Commission sought advice from the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). This is in line with the REACH REFIT evaluation[19] in which the Commission proposed to "*enhance the role of ECHA's RAC, involving also social partners, to provide scientific opinions under the OSH legislation while respecting the role of the ACSH*" with the aim to clarify the interface between REACH and other pieces of EU legislation.

The purpose of this impact assessment is to verify, on the basis of available socioeconomic data, the robustness of ACSH opinions and, eventually to consider some complementary measures, which could be proposed, based on further scientific information.

Member States authorities, employers' and workers' representative bodies within the tripartite ACSH strongly anticipate the legal clarity and increased protection which would be the result of new or revised OELs of these substances.

The analysis presented in this document should be read in conjunction with the earlier impact assessment (IA)[20] for the first proposal, which provided an exhaustive consideration of the CMD, the policy and legal context.

The most essential points are carried over and supplemented by additional information and analysis regarding these three additional carcinogens.

[18] COWI (2019), collecting most recent information for a certain number of substances with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendements of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

[19] See footnote 11

[20] Commission Staff Working Document, Impact Assessment accompanying the proposal for a Directive of the European Parliament and the Council amending Directive 2004/37/EC on the protection of workers from the risks related to carcinogens or mutagens at work (SWD(2016)152final). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2016:0152:FIN

2. PROBLEM DEFINITION

2.1. What is/are the problems?

As mentioned in section 1, 52% of annual occupational deaths in the EU are currently attributed to cancer. Furthermore, carcinogenic and mutagenic substances lead not only to cancers, but also to other important health problems. For example, exposure to benzene, in addition to leukaemia, also causes leukocytopenia, lymphocytopenia, neutrocytopenia and thrombocytopenia. More information about all the health effects for the three substances addressed in this initiative are available in table 1.

As mentioned in the previous section, more than 1 million workers are currently exposed to acrylonitrile, nickel compounds or benzene. If no action is taken at the EU level, these workers will continue to run the risk of contracting a cancer or other severe health problems.

Furthermore, ineffective prevention of the exposure to carcinogens entails negative consequences for business such as higher costs and reduced productivity due to absenteeism, lost expertise and distorted competition. For Member States, this also leads to increased social security costs and missed tax revenues.

The problem tree below summarises the main drivers behind the problem and the resulting consequences for workers, business and Member States:

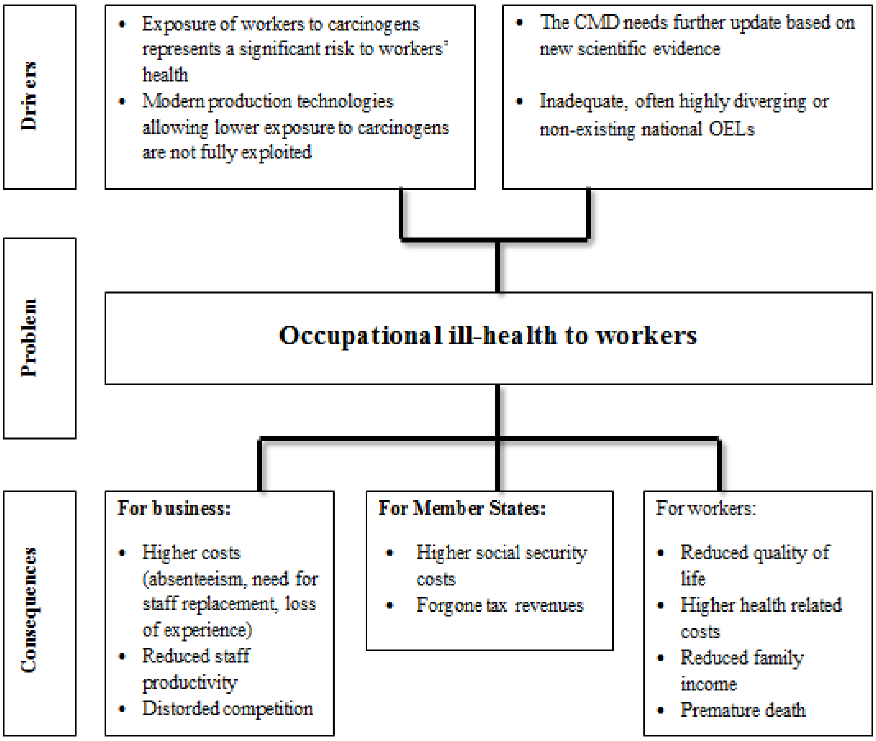

Figure 2: Problem tree

2.2. What are the problem drivers?

2.2.1. Exposure of workers to carcinogens represents a significant risk to workers' health

This section presents an overview of the estimated numbers of workers exposed to the substances subject to this initiative and a short explanatory summary for each substance. More detailed information is provided in annex 6.

Different sources compile different estimates of the total number of exposed workers. For the purpose of this impact assessment, for each substance the most reliable number has been taken forward for the baseline scenarios and for the cost-benefit assessments related to the retained options for establishing limit values.

Table 1: Summary of estimates taken forward for the assessment of options

Carcinogen	Exposed workforce (number of workers)	Health effects caused	Major occupational exposure route
Acrylonitrile	**10,000 – 33,000**	- Brain, stomach, tongue, intestines and mammary gland cancer - Nasal irritation	Primary route of exposure is through inhalation, although exposure can also occur through dermal contact.
Nickel compounds	**~87,500**	- Lung and nasal cancer - Pulmonary morbidity and miscarriage	Primary route of exposure is by dermal contact or by inhalation of aerosols, dusts, fumes of mists containing nickel. Dermal contact may also occur with nickel solutions.
Benzene	**1,012,500**	- Leukaemia - Leukocytopenia, lymphocytopenia, neutrocytopenia and thrombocytopenia	Benzene is readily absorbed by all routes (inhalation, dermal and oral), of which inhalation is the most important route of occupational exposure.
Total workforce assessed:	**~ 1,121,500**		
Based on COWI study (2019)			

Acrylonitrile

Acrylonitrile is widely used in the aircraft, defence, aerospace and automotive sectors.[21] This substance is particularly important to ensure a transition to technologies which are more environmentally friendly. More information is available at the annex 6.

[21] https://www.petrochemistry.eu/sector-group/acrylonitrile/

As shown in the table 1, between 10,000 and 33,000 workers are estimated to be exposed to acrylonitrile at their workplace. Such an exposure can lead to brain, stomach, tongue, intestines and mammary gland cancer, but also to other health problems like nasal irritation. Although inhalation is considered as the primary route of exposure, workers can also be exposed through dermal contact.

Nickel compounds

Nickel compounds are used in a wide variety of sectors and are usually supplied in granule, powder or liquid form. More information about the uses of nickel compounds can be found at annex 6.

Table 1 shows that around 87,500 workers are currently estimated to be exposed to nickel compounds. This may have dramatic consequences as exposure to nickel compounds can lead to lung and nasal cancers but also pulmonary morbidity and miscarriage. The primary route of exposure is by dermal contact or by inhalation of aerosols, dusts, fumes of mists containing nickel.

Benzene

Benzene is produced in petroleum refinery and chemical plant processes and is used as an intermediate in the production of a wide range of chemical substances. Benzene is also used in the manufacturing of some types of rubbers, lubricants, dyes, detergents, drugs, and pesticides.[22] More information about the production and the uses of benzene are available in annex 6.

It is assumed that more than 1 million workers are still exposed to benzene and could therefore contract different hazardous diseases like leukaemia, as shown in the table 1. Benzene is readily absorbed by all routes (inhalation, dermal and oral). Inhalation is the most important route of occupational exposure.

The table 2 below shows the current and future burden of cancer and other health effects related to the occupational exposure to the three substances under consideration. Given the long latency period of the illnesses considered in this impact assessment, the future health burden is estimated over a 60 year period.

However, the disease burden on workers is likely to be underestimated due to several limitations of the data/calculations, which are further explained in the analytical challenges section of the annex 4. For instance, the COWI study does not quantify the burden of all cancers and other adverse health effects but only of those which are known to be caused by the lowest exposures (so-called most sensitive endpoints). When exposed to these substances, workers may develop additional types of cancer and other diseases which could be prevented by establishing an EU-wide OEL as mentioned in the RAC opinions for acrylonitrile[23], nickel compounds[24] and benzene[25]. The table 2 specifies the health effects

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[22] ECHA (2018), Background document in support of the Committee for Risk Assessment (RAC) evaluation of limit values for benzene in the workplace. ECHA/RAC/O-0000001412-86-187/F.
Available at: https://echa.europa.eu/documents/10162/13641/benzene_bg_annex1_en.pdf/37b38de4-0e36-6058-eaa4-1ffc56938831

[23] RAC opinion on acrylonitrile available at: https://echa.europa.eu/documents/10162/13641/acrylonitrile_opinion_en.pdf/102477c9-a961-2c96-5c4d-76fcd856ac19

[24] RAC opinion on nickel and its compounds available at: https://echa.europa.eu/documents/10162/13641/nickel_opinion_en.pdf/9e050da5-b45c-c8e5-9e5e-a1a2ce908335

[25] RAC opinion on benzene available at: https://echa.europa.eu/documents/10162/13641/benzene_opinion_en.pdf/4fec9aac-9ed5-2aae-7b70-5226705358c7

which have been quantified and not quantified. As these three substances fall under the CMD, in order to prevent the whole range of health problems, an OEL can only be established under this directive.

Furthermore, occupational cancers may develop decades after exposures – including during retirement – complicating the possibility of identifying a causal link, which could lead to underestimation of the disease burden.

For the specific case of benzene, table 2 shows that even with an existing EU OEL, a high number of workers can still develop leukaemia and other serious illnesses in the absence of further EU action.

Table 2 : Current and future disease burden related to occupational exposure to carcinogens (number of cases)

Carcinogen	Health effects caused	Current* disease burden (quantified)	Future** disease burden (quantified)
Acrylonitrile	**Brain cancer (quantified)**, stomach, tongue, intestines, mammary gland cancer (not quantified)	0.04 – 0.15	1 – 12
	Nasal irritation (quantified)	1.6 – 9.4	73 - 408
Nickel compounds	**Lung cancer (quantified)**, nasal cancer (not quantified)	12	149
	Pulmonary morbidity (quantified)	135	718
	Miscarriage (quantified)	12	90
Benzene	**Leukaemia (quantified)**	30	300
	Leukocytopenia (quantified), lymphocytopenia, neutrocytopenia and thrombocytopenia (not quantified)	25	237
TOTAL		**215.64 - 223.55**	**1568 - 1914**
* *Incidence in 2018* ** *The future health burden is estimated over a 60 year period*			
Based on COWI study (2019)			

2.2.2. New scientific and technical evidence is available that could lead to updating of existing or establishment of new OELs

Under the CMD, employers must identify and assess risks to workers associated with exposure to carcinogens and mutagens, and must prevent exposure where risks occur. Substitution to a non- or less-hazardous process or chemical agent is required where this is technically possible. Where carcinogens cannot be substituted they must, so far as is technically possible, be manufactured and used in a closed system to prevent exposure. Where this is not technically possible either, worker exposure must otherwise be reduced to as low a level as is technically possible. This is the so-called minimisation obligation under Article 5 of the CMD.

For some chemical agents, the CMD establishes binding OELs at the EU level. The fact that OELs are established does not affect the obligations of the employer to comply with other rules, including to reduce the exposure of his/her workers to carcinogenic and mutagenic substances to as low a level as is technically possible (minimisation of the occupational exposure).

The existence of OELs provides clarity and OELs are very relevant benchmarks for employers enabling them to know exactly the levels above which exposure cannot occur. OELs also allow employers to determine the level below which their risk management measures should aim to comply with the obligation to reduce the exposure to as low a level as is technically possible. To this end, Safety Data Sheets (SDS), and more especially their section 8.1, are very important for downstream users to identify and apply appropriate measures in order to adequately control the risk of the chemicals at their site[26].

OELs also support enforcement authorities in controlling that employers are putting in place the relevant risk management measures, including those that could contribute to lower the exposure below the OELs.

Under the CMD, the European Parliament and the Council shall set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.

For the substances covered in this impact assessment, the scientific advice has been provided by RAC which adopted its three opinions on 9 March 2018[27] [28] [29]. The tripartite ACSH also adopted opinions for all three on 4 June 2019[30]. It is therefore appropriate to consider updating the CMD based on the above-mentioned information. Further information on the scientific advice and ACSH opinions is provided in annexes 1 and 2, respectively.

Among the three substances addressed in this impact assessment, only benzene has already an EU wide OEL of 3.25 mg/m³ dated from 2004. Although this EU OEL already provides among others clarity and support enforcement by authorities as explained above, the most recent scientific and technical evidence indicates that it should be updated. This is in line with the CMD obligation to revise OELs whenever this becomes necessary in the light of more recent scientific data.

2.2.3. Diverging national OELs create different competing conditions and protection levels across the EU

The 2004 benzene OEL enabled to set a minimum common protection for all the workers dealing with this substance across the EU and limited the different competing conditions. The table 3 below, which lists among others the lowest and highest binding national OELs, shows that the Netherlands have set an OEL more than four times more stringent than the EU wide OEL. We can also deduce from this table that 10 countries adopted a level stricter than the EU OEL. Although differences in national OELs for benzene remain, this EU OEL limits the scope for divergences. If no EU OEL had been set, we cannot exclude that some Member States would not have established a national OEL yet.

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[26] ECHA (2018), Guide on Safety data sheets and exposure scenarios.
Available at: https://echa.europa.eu/documents/10162/22786913/sds_es_guide_en.pdf

[27] See footnote 23

[28] See footnote 24

[29] See footnote 25

[30] The links to these ACSH opinions are available at the Annex II

Although there is still no EU wide OEL for acrylonitrile, 21 Member States have already set a national OEL in their own legislation while 7 Member States have no OELs yet. These national OELs range from 0.5 mg/m³ in Latvia to 7 mg/m³ in Slovenia and Slovakia.

In the absence of any EU wide OEL for nickel compounds, the table below shows that only a few Member States have already set an OEL. However, 19 out of the 23 Member States with no single national OEL for nickel compounds have a mix of OELs for some or all of these compounds. Moreover, the strictest OEL for nickel compounds is eight times lower than the highest limit value.

Table 3 : National OELs in EU Member States

Carcinogen	Lowest (strictest) national binding OEL (mg/m³)	Highest (least strict) national binding OEL (mg/m³)	Member States with no OEL
Acrylonitrile	0.5 LV	7 SI, SK	7 BG, CY, HR, IT, LU, MT, NL*
Nickel compounds** (inhalable fraction)	0.03 DE	0.25 PL	23*** AT, BE, CY, CZ, DK, EE, EL, ES, FI, FR, HU, HR, IE, IT, LT, LU, LV, MT, NL, PT, SI, SK, UK
Benzene	0.7 NL	3.25 BE, BG, CY, ES, EL, FI, FR, HR, IT, LT, LU, LV, MT, PT, RO, SI, SK, UK	0

* *In the Netherlands, in the absence of national OEL, industry is responsible for setting individual OELs. Among these substances with no national OEL is acrylonitrile.*
*** Single OEL for all the nickel compounds*
**** 19 Member States have OEL(s) for some or all nickel compounds*
Based on COWI study (2019)

As shown in the table 3, the disparities between the existing national OELs for the three substances are high, which leads to different level of protection of the EU workers. In addition to this main consequence, such differences also cause complications for businesses operating in different Member States and bring confusion to cross-border companies which have to deal with highly diverging OELs. To a lesser extent, these disparities could also provide potential incentive for companies to locate their production facilities in Member States with the lower standards, which would prevent the smooth functioning of the internal market. Such disparities may also be a brake to the freedom of movements of workers, as they could renounce to accept a job in another Member State, for fear to receive weaker health and safety protection. Annex 5 provides an overview of all national OELs in EU Member States for the substances considered under this initiative.

2.2.4. Modern production technologies allowing lower exposure to carcinogens or mutagens are not fully exploited

Although modern production technologies allow to reduce further the occupational exposure to carcinogenic and mutagenic substances in the workplace, their implementation is not yet generalised in all the companies dealing with the three substances addressed in this initiative. One possible reason is that decisions of business are often influenced by short-term cost assumptions rather than long-term benefits.

For example, as regards acrylonitrile, although a significant part of the companies have already a closed system in place, some companies having laboratories using this substance mainly use hoods as ventilation system. Moreover, it is assumed that companies operating at low concentration levels usually have full enclosure local exhaust ventilation (LEV) while the others have partial enclosure or open hood LEV[31]. Companies working at higher levels of exposure should therefore invest in full enclosure LEV where possible.

According to a consultation survey carried out in the framework of the COWI study, companies indicated in which types of risk management measures (RMMs) they would invest to comply with OELs of 0.01 and 0.03 mg/m³ for nickel compounds. As an example, 30% of the companies that replied to this survey would make investments in partial hoods to comply with an OEL of 0.03 mg/m³. This tends to prove that companies do not always use the most modern production technologies allowing to reduce the exposure to carcinogens or mutagens.

A similar consultation survey was conducted for companies dealing with benzene. During this survey, several companies indicated that it was possible to reduce further the exposure of workers to benzene, meaning that they do not use the most modern production technologies yet.

2.3. How will the problem evolve?

In the absence of EU action, it is estimated that workers exposed to these substances will continue to face the risk of contracting occupational cancer or other adverse health effects. Estimations on the numbers of cancer and other hazardous diseases cases and their associated health costs over a 60-years period in case no action is taken are contained in the table 4 below (baseline scenario).

The general obligations set by the CMD, employers' actions and measures adopted by Member States contribute overall to lowering exposures. Exposure levels have generally been decreasing in the past years and this positive trend could continue in the future. Substitution may be possible for some carcinogens in the future, also the numbers of workers in the industries using these carcinogens may change, and technological developments could facilitate lower exposure concentrations.

Future forecasts in this area are however far from certain due to scarcity of relevant data and the fact that market forces such as raw material and energy prices, developing technology, as well as regulatory changes can drive decreases or increases in use which are not easy to predict. Even if trends were overall positive, as explained above, the existing employers' practices as well as protective measures at Member State level do not always reflect available scientific and technological knowledge. For that reason, assumptions are based on the legal provisions contained in the CMD, including the minimisation requirements, but also on other data including information gathered from the stakeholders. The objective has been to define a baseline scenario as close as possible to the future situation. However, it is very challenging to anticipate all the developments over such a long period. Further demographic

[31] See footnote 18

changes increase the life expectancy of workers exposed and, therefore, the chances to develop the illnesses mentioned in table 2. More information about the past and future trends regarding the number of workers exposed and the exposure concentrations are available in Chapter 6.

Member States usually do not inform the Commission on their intentions to revise existing or determine new OELs in their national legislation. However, national administrations represented in the ACSH are aware of the preparatory work at EU level and therefore it is likely they will await its results in order not to duplicate efforts.

Table 4 - Estimated number of expossed workers, expected number of cancers and other hazardous diseases cases and related health costs in case no action is taken (baseline scenario), over a 60 years period

Carcinogen	No. of exposed workers[32]	Expected no. of cancer cases	Expected no. of cases of other adverse health effects	Estimated health costs	Possible underestimations (non exhaustive list)
Acrylonitrile	10,000 - 33,000	1 - 12	73 - 408[33]	291,000 – 7,446,000	Some health endpoints (neurotoxicity, cancer sites other than brain) could not be quantified
Nickel compounds	~87,500	149	808[34]	52,674,000 – 124,800,000	Some health endpoints (sinonasal cancer) could not be quantified
Benzene	1,012,500	300	237[35]	202,000,000 – 331,000,000	Some health endpoints (haematotoxic effects) could not be quantified
Total	**~ 1,121,500**	**450 - 461**	**1118 - 1453**	**254,965,000 – 463,246,000**	

Source: COWI study (2019)

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

Article 153 TFEU empowers the EU to support and complement the activities of the Member States as regards improvements, in particular of the working environment to protect workers' health and safety and to adopt, by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. On the basis of this

[32] Estimates
[33] Nasal irritation (mortality rate: 0%)
[34] Pulmonary morbidity: 718 (mortality rate: 0%) / miscarriage: 90 (mortality rate: 0%)
[35] Leukocytopenia (mortality rate : 0%)

provision, Article 16 (1) of the CMD provides a specific legal basis for action, allowing for adoption of limit values in respect of those carcinogens or mutagens for which this is possible, having regard to the available information, including scientific and technical data.

3.2. Subsidiarity: Necessity and added value of EU action

Scientific knowledge about carcinogenic chemicals is constantly developing and technological progress enables improvements in protection of workers. In order to ensure that the mechanisms for protecting workers from carcinogenic chemicals established in the CMD are as effective as possible, the Directive needs to be kept up to date with those developments. Updating the CMD to take account of newer scientific evidence is an effective way to ensure that preventive measures would be updated accordingly in all Member States.

The ex-post evaluation of the European Union occupational safety and health Directives[36] (REFIT evaluation) emphasizes that chemicals classified as carcinogens and mutagens continue to be manufactured across the EU and workers in manufacturing but also downstreams users continue to be exposed to them. The main conclusions of this evaluation indicates that the CMD is considered as of high relevance. Following concerns raised by different stakeholders' groups in the evaluation process and in the National Implementation Reports, the need to adopt limit values for more substances should be considered. These additionals OELs should lead to a better chemical risk management in the future.

This initiative is the fourth update of the CMD aiming to set additional OELs for all those carcinogens or mutagens for which this is possible in the light of the available information, as required by the article 16 of the CMD. In the future, the Commission will continue to evaluate the need to propose additional OELs in the CMD and to propose additional amendments when needed, in collaboration among others with the ACSH.

Amending the CMD can only be done by action at EU level and it presents an EU added value in several respects:

Improved clarity and enforcement

Establishing new OELs for acrylonitrile and nickel compounds will provide common reference points that are used as a practical tool by employers, workers and enforcers to assess compliance with the general CMD requirements. OELs can also be used by process plant and machinery designers when planning new or considering alterations to existing process plants.

Clear support for establishing OELs for the substances subject to this initiative has been expressed from key stakeholders as it clearly results from the two phases of the consultation of the social partners and the opinions of the tripartite ACSH.

Ensuring a similar minimum level of protection across the EU

[36] Commission Staff Working Document "Ex-post evaluation of the European Union occupational safety and health Directives (REFIT evaluation). Available at: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52017SC0010

The CMD aims to improve workers' health and safety by protecting them against risks arising or likely to arise from exposure to carcinogens or mutagens at work. This objective is in line with the European Pillar of Social Rights and the commitment of President von der Leyen to step up the fight against cancer in the context of a European plan against cancer.

Limit values under the CMD are an important component of the general arrangements for the protection of workers[37]. As laid down in Article 16 of the CMD, limit values should be established for all those carcinogens and mutagens for which the available information, including scientific and technical data, makes this possible. Such OELs should also be revised whenever this becomes necessary in the light of more recent scientific data[38].

As mentioned in annex 8 related to the process for setting OELs under the CMD, it is not realistic to set an OEL for each hazardous chemical that may be used at the workplace. Therefore, the Commission identified acrylonitrile, nickel compounds and benzene as priority substances, following the procedure detailed in annex 8. This list of substances to be addressed in the 4th revision of the CMD has been approved by the Social Partners in the context of the formal two-stage consultation for which more information is provided in annex 2.

As highlighted in section 2.2.3., the difference between the national OELs may be very high. For instance, national OELs for acrylonitrile range from 0.5 mg/m^3 to 7 mg/m^3, meaning that some Member States have set limit values fourteen times lower than others. And in addition to that, 7 Member States have no OELs yet to prevent workers' exposure to this substance.

Lack of EU action will most likely mean that there will remain Member States where no limit values exist for certain carcinogens or where those values are too high to ensure adequate worker protection. A minimum standard across the EU will not be ensured, to the detriment of worker protection.

With regard to the specific case of benzene, although an EU OEL already exists, its revision will ensure a more appropriate minimum level of protection across the EU.

Contribution to a level playing field

Employers' organisations stressed in their response to the social partner consultation that setting EU OELs helps to provide a level playing field for industry. The costs of complying with lower national levels are generally higher and entail, therefore, a competitive advantage for enterprises operating in markets with no or less stringent national OELs.

Setting EU OELs will not completely eliminate the differences between Member States. Indeed, they retain the possibility to adopt lower limit values as shown for benzene in table 3. However, it will limit (acrylonitrile and nickel compounds) or further limit (benzene) the scope for divergences and enhance certainty that there is a core definition and/or enforceable exposure limit for all concerned carcinogens in all Member States.

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[37] Recital 13 of Directive 2004/37/EC

[38] See footnote 37

Assuming burdens at EU level related to derivation of limit values

The process of establishing limit values is very complex and requires a high level of scientific expertise. An important advantage of setting OELs at EU level is that it eliminates the need for Member States to conduct their own scientific analysis with likely substantial savings on administrative costs. These resources saved could instead be dedicated to improve further the occupational health and safety policies in each Member State.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

The main general objective of this initiative is to ensure to the workers the right to a high level of protection of their health and safety at work, as laid down in the principle 10 of the European Pillar of Social Rights[39], and to prevent death caused by work-related cancer and other health problems as mentioned in the Commission Communication on "Safer and Healthier Work for All"[40].

4.2. Specific objectives

The specific objectives are:

- To further improve protection from occupational exposure to carcinogens and mutagens in the European Union;
- To increase the effectiveness of the EU legal framework by updating it on the basis of scientific expertise;
- To ensure more clarity, facilitate implementation, and contribute towards a better level playing field for economic operators by adopting minimum requirements at the European level. The existence of OELs provides clarity by determining among others the maximum level of exposure with which employers must comply. However, complying with the OELs does not prevent the employers from their other obligations pursuant to the CMD, including the reduction of the exposure as low a level as is technically possible.

4.3. Consistency with other EU policies

Charter of Fundamental Rights of the EU

The objectives of the initiative are consistent with Article 2 (Right to life) and Article 31 (Right to fair and just working conditions) of the EU Charter of Fundamental Rights.

REACH Regulation

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[39] See footnote 5
[40] See footnote 6

The REACH Regulation[41], entered into force in 2007, establishes among others two distinct EU regulatory approaches that are restrictions and authorisations. Restrictions enable the EU to impose conditions on the manufacturing, placing on the market and/or use of substances, in mixtures or in articles, and authorisation is designed to ensure that risk of substances of very high concern (SVHCs) is properly controlled while promoting progressive substitution by suitable alternatives that are economically and technically viable[42].

The applicable provisions of REACH authorisation and/or restriction of the chemical substances under consideration in this assessment, are as follows[43]:

- Restriction: all uses of benzene and its mixtures with some exemptions, the use of nickel and its compounds in jewellery and articles which are intended to come into contact with the skin, the use of acrylonitrile and its mixtures supplied to the general public.
- Authorisation: none of these substances are subject to authorisation under REACH.

More information about the REACH restrictions for the three substances is available in annex 10.

Having an OEL under the CMD plays an important role in the reduction of worker exposure to benzene. Industrial processes covered by other EU legislations which set up specific quantity of emission of benzene, are indeed not subject to the REACH restriction for this substance[44].

Setting an OEL for nickel compounds under the CMD will also enable to reduce the exposure of workers to this group of substances.

As the REACH restriction for acrylonitrile does not concern the industrial uses, the setting of an OEL for this substance under the CMD will improve the protection of workers as they are not covered by the REACH restriction.

Europe's Beating Cancer Plan

In her political guidelines for the next European Commission[45], President von der Leyen recognized that there is much more the European Union can do about cancer and committed to put forward a European plan to fight cancer. On 4 February 2020, the Commission launched an EU-wide public consultation on Europe's Beating Cancer Plan on the occasion of a conference entitled "Europe's Beating Cancer Plan: Let's Strive for More"hosted in the European parliament.

Europe's Beating Cancer Plan will be structured around four pillars: prevention, early diagnosis, treatment and follow-up care. This proposal is fitted with the objectives of the prevention pillar such as measures to reduce environmental risk factors, for instance pollution and exposure to chemicals, and in particular the reduction of the exposure to carcinogens in the workplace.

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[41] See footnote 9

[42] Communication from the Commission on Commission General Report on the operation of REACH and review of certain elements – Conclusions and Actions. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

[43] A more detailed list of REACH status of the concerned chemical agents can be found in Annex 10

[44] More information about the REACH restriction for benzene is available in Annex 10.

[45] See footnote 2

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. Process for setting binding OELs and associated provisions under CMD

A simplified outline of the process for the development of EU OELs for carcinogens and mutagens is set out here. A more detailed description is provided for in annex 8.

As mentionned in Chapter 1, the selection of the specific three substances considered in this impact assessment was based on a consultative approach, including opinions issued by the tripartite ACSH and a formal two-stage consultation of the social partners.

It was agreed by all relevant stakeholders, taking into account factors such as the potential to cause adverse health effects, degree of evidence of such effects, as well as their severity, potency and reversibility, that the three substances are of high relevance for the protection of workers. The Commission's intention to prepare for the establishment of OELs for those priority carcinogens was confirmed and encouraged by all the stakeholders.

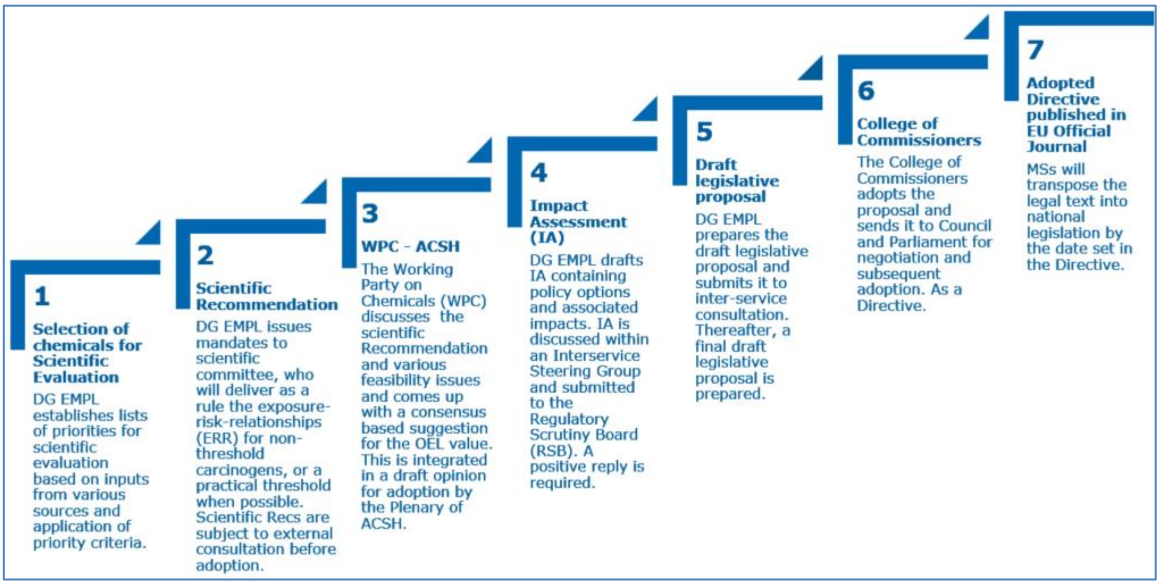

Figure 3: simple representation of typical EU OEL setting procedure (Source: ECHA website)

5.2. Description of the retained policy options for establishing binding OELs under the CMD

The reference limit values per substance are presented below.

In addition to the baseline scenario, options for OELs have been considered at the level proposed by the ACSH, including the transitional OELs, and at additional reference points (e.g. the strictest limit value observed among Member States, OELs derived by the RAC). It needs to be noted that the most stringent national OEL might not always be feasible as an EU standard for the following reasons: firstly, the substances subject to this proposal are used in many different industries, and for some industries it might be difficult to comply with strict OELs due to their specific production processes. Member States with the strictest OELs might not host the industries having problems to comply with the strictest OEL. Secondly, industries are at different stages in their maturity and use varying technologies and processes. Thus, in Member States and industries with more advanced and automated production processes it would be easier to reach a low OEL. However, this cannot prevent the European Union to set a similar and adequate minimum level of protection across the EU. These considerations are taken into account in the analysis substance by substance.

All the OELs recommended by the ACSH, including the transitional limit values, as well as the OELs derived by the RAC, are covered by the different scenarios for each substance and are mentioned in the table 5 below. The OELs unanimously recommended by the three Interest Groups of the ACSH (Employers, Workers and Governments) have been established through scientific, technical and socioeconomic discussion. However, the costs and benefits of the combination of a targeting OEL and a transitional OEL have not been assessed in the COWI study. Therefore, it has not been possible to consider them as individual policy options. However, it is reasonable to consider that accompanying an OEL with transitional measures would have limited impacts on the benefits and relatively higher impacts on the costs. Furthermore, the OELs recommended by the ACSH as transitional OELs are covered by the policy options.

For acrylonitrile, an OEL at the level of the lowest limit value in the Member States and another OEL two times higher the OEL recommended by the ACSH and the RAC have been retained as policy options . These two policy options for acrylonitrile are reference points aiming to establish whether the OEL recommended by the ACSH is appropriate to follow.

As in the previous impact assessments, several other options than the retained policy options mentioned above have been discarded as they were considered as disproportionate or less effective in reaching the objectives of this initiative. More information about these discarded options is available in annex 9.

Table 5: Options matrix of OELs[46]

Carcinogen	Option 1 Baseline	Other options		
		Option 2	Option 3	Option 4
Acrylonitrile	no EU OEL	0.5 mg/m^3	1 mg/m^3 (ACSH / RAC)	2 mg/m^3
Nickel compounds (inhalable)	no EU OEL	0.03 mg/m^3 (RAC)	0.05 mg/m^3 (ACSH)	0.1 mg/m^3 (ACSH transition value)
Benzene	1 ppm (3.25 mg/m^3) (current EU OEL)	0.05 ppm (0.16 mg/m^3) (RAC)	0.2 ppm (0.66 mg/m^3) (ACSH)	0.5 ppm (1.62 mg/m^3) (≈ ACSH transition value)

[46] OELs at 8hr TWA

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

Different policy options presented in the options matrix in table 5 have been compared based on the methodology outlined in detail in annex 8. Other options than those supported by the ACSH in its opinions, such as the OEL recommended by RAC, are presented as reference points for the assessment of the ACSH options, to establish whether these are appropriate to follow.

Analytical methodology

The introduction of an OEL is expected to result in a reduction in the occupational exposure to the carcinogen concerned. The extent of such reduction depends on the current levels of exposure, as well as on the projected future levels of exposure in the absence of the proposed measure, i.e. the "baseline scenario".

The baseline or "no policy change" option includes all relevant EU-level and national policies and measures which are assumed to continue being in force in the absence of further EU action. The baseline also takes into account as much as possible how the problem would evolve, considering legal provisions contained in the CMD but also all relevant societal, economic and technical developments that would probably occur in the following decades. For instance, the expected decrease of the use of petrol due to the gradual change to electric vehicles is taken into account. It also includes the existing national OELs, the current number of workers exposed and its evolution over time, the current and future exposure levels, the current risk management measures, the voluntary industry initiatives, the development of new technologies/growing use of substitutes, the future use of the substances and any other relevant factors.

For a given reduction in exposure levels, it is then necessary to estimate the expected decrease in the incidence of cancer and non cancer cases over a given timeframe to the carcinogen in question. This requires estimates of the risks of carcinogenicity and other adverse health effects, which can be derived from the existing toxicological and epidemiological literature, as well as information about the current level of worker exposure (number of workers, level, duration and frequency of exposure).

The health benefits of avoided cancer and non-cancer diseases registrations and deaths can then be expressed in monetary terms by applying standard evaluation methods[47], in line with the Better Regulation Toolbox guidance. These health benefits of implementing new or revised OELs are calculated in terms of the costs of ill health avoided.

These monetised health benefits can in turn be compared to the expected monetary costs that would have to be incurred in order to comply with the proposed OEL. The estimate of the costs was made based on a literature research and data obtained from stakeholder contacts and take into account the following factors: the RMMs needed to comply with the proposed OEL, the costs of these RMMs for each company, the life span of the RMMs and the number of companies. The monetised health benefits are also compared to the other costs, including costs for public authorities, as well as to the potential effects on the market for the substance by the imposition of an OEL.

[47] The valuation of health impacts was undertaken based on two approaches. Approach one is the application of a single willingness to pay (WTP) value to each case and approach two is the use of disability adjusted life years (DALYs) and their monetisation.

The benefits and costs of possible OELs are measured against the baseline, meaning that only marginal costs and marginal benefits are taken into account (for example, additional costs added to the current costs to comply with REACH regulations).

Given the complementarity between the regulation under REACH and the minimum requirements established through the CMD, the past and present REACH measures have been specifically taken into account in assessing the baseline and the impacts of the proposed CMD measures for all substances in this report.

More information about the analytical methodology, but also some analytical challengens arising from this cost-benefit analysis, are further discussed in annex 4.

6.1. Acrylonitrile

Baseline

Approximatively 10,000 to 33,000 workers in the EU are exposed to acrylonitrile, depending on the sources of data used for the calculation[48].

The sectors using acrylonitrile that have been examined for this impact assessment are industrial manufacturing, manufacture of textiles, leather and fur, manufacture of bulk, large scale chemicals (including petroleum products), manufacture of fine chemicals, formulation of preparations and/or re-packaging (excluding alloys), manufacture of rubber products, manufacture of plastics products (including compounding and conversion), manufacture of computer, electronic and optical products, electrical equipment, building and construction work, health services, professional use, scientific research and development.

Acrylonitrile is not subject to authorisation according to Annex XIV of REACH but its use is restricted under Entry 28 of Annex XVII under the REACH Regulation[49]. However, this restriction only concerns the general public and not workers. More information about this restriction can be found in annex 10 of this impact assessment. There is not yet any OEL for acrylonitrile at the EU level.

It is assumed that the number of exposed workers remained constant in the past and will remain unchanged in the future. Annual declines of 3%[50] and 0%[51] in exposure concentrations are respectively assumed for the current and future disease burdens. In addition to that, a 5% staff turnover is taken into account for calculation purposes. The future disease burden only reflects cases occurring as a result of future exposure, leading to underestimated numbers of cancer[52].

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[48] Carex EU and Acrylonitrile Sector Group data.

[49] Substances listed under Entry 28 are not to be placed on the market for use by the general public ‘when the individual concentration in the substance or mixture is equal to or greater than’ either the ‘relevant specific concentration limit’ specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or the ‘relevant generic concentration limit’, specified in Part 3 of Annex I to Regulation (EC) No 1272/2008. Suppliers shall ensure before placing on the market that the packaging of such substances and mixtures is marked as ‘Restricted to professional users’

[50] COWI study (based on a study on workers exposed to acrylonitrile and published in the Scandinavian Journal of Work, Environment & Health).

[51] The null trend for the future exposure concentrations is explained among others by the fact there is no data suggesting a change of the exposure levels.

[52] Additional information about the analytical challenges leading to potential over- and underestimations is available at Annex IV, section 3.

In the absence of any further action, up to 12 new brain cancer and 408 nasal irritation cases resulting from future exposure are estimated to occur in the coming 60 years, which would cost respectively up to €5,692,000 and €1,754,000. With regard to brain cancer, a 30 years latency period and a mortality rate of 80% are assumed. It should be borne in mind that only two health endpoints (brain cancer and nasal irritation) have been used in this impact assessment, which could lead to underestimate even further the exact number of cancer cases and other adverse health effects.

Table 6: Baseline scenario over 60 years for acrylonitrile

Types of cancer caused	Brain (quantified), stomach, tongue, intestines, mammary gland (not quantified)
Other adverse health effects	Nasal irritation (quantified)
No. of exp. workers	10,000 to 33,000
Change exp. level	Past: 3% Future: 0%
Change no. of exp. workers	Past: 0% Future: 0%
Current disease burden (CDB) - no. of brain cancer cases	0.04-0.15
Future disease burden (FDB) - no. of brain cancer cases	1–12
CDB no. of other adverse health effects	Nasal irritation: 1.6-9.4
FDB no. of other adverse health effects	Nasal irritation: 73–408
Exp. no. of deaths FDB cancer	0.8 – 9.6
Exp. no. of deaths FDB other adverse health effects	Presumed 0
Monetary value FDB brain cancer	Method 1: €417,000–€5,692,000 Method 2: €269,000–€3,678,000
Monetary value FDB other adverse health effects	Method 1: €22,000–€121,000 Method 2: €314,000–€1,754,000
Based on COWI study (2019) **Workforce turns over at 5% p.a.*	

Impacts of the policy options

The table 7 below shows the multi-criteria analysis, summarizing both the monetised impacts as well as those that are assessed qualitatively.

In its opinion[53], RAC derives a limit value of 1 mg/m³ (0.45 ppm) which assumes a mode of action-based threshold for the carcinogenic effects of acrylonitrile. RAC also recognises that "*there may be occupational tasks at industrial sites presenting a short term acute exposure risk*". For that reason, It also

[53] See footnote 23

derives a short-term exposure limit (STEL) of 4 mg/m³ (1.8 ppm). The costs and benefits for STEL values could not be monetised for acrylonitrile. However, the three Interest Groups in the ACSH opinion recommended the same OEL and STEL as RAC accompanied with a 4-years transition period starting from the entry into force of the Directive revising the CMD.

Although the main route of occupational exposure to acrylonitrile is by inhalation of the vapour, RAC noted that dermal exposure is also possible. Acrylonitrile can indeed readily penetrate the skin. For that reason, RAC recommended to set a skin notation. This skin notation has also been recommended by the ACSH.

Compliance cost levels for companies generally depend on the extent to which exposures are currently close to the required OELs. The higher the difference between the current exposure levels and the required OEL is, the higher the investments in RMMs will be. Since the exposure levels in the different sectors using acrylonitrile are already very low, the compliance costs for companies should be very limited.

Complying with an OEL of 1 mg/m³ as recommended by the RAC and the ACSH would cost to the employers €28,000,000 over a 60 years period, which corresponds to between 0.02% and 0.07% of the turnover, depending on the current average exposure and the size of the company. This is not considered to be significant enough as to force companies to cease operating. However, these compliance costs have to be entirely considered as one-off costs which will be dedicated to investements in LEVs. A transition period could therefore be necessary to mitigate the adverse effects of such upfront effort by enabling companies to anticipate the changes, more gradually introduce improvements and plan the necessary investments. In the event of the introduction of an OEL of 0.5 mg/m³, compliance costs would represent up to 0.12% of the turnover and could, therefore, have more consequences for companies.

Some of the costs included in the estimated compliance costs concern RMMs that may be required in any case to control exposure to other substances, leading to a possible compliance costs overestimation.

Given their lower turnovers, SMEs usually encounter more difficulties to comply with lower OELs than the large companies. For an OEL of 1 mg/m³, it is estimated that SMEs will have to invest up to 0.07% of their 60-years turnover while larger companies could only need to invest 0.02% of their turnover. The estimated costs for this scenario therefore remain relatively low and no SMEs are expected to close down. However, as mentioned above these costs will be one-off costs and a transition period could be needed for companies, especially SMEs that might need more time to manage the investments. In the event that the OEL would be set at 0.5 mg/m³, SMEs could face compliance costs of up to 0.12% of their turnover.

The impact of introducing any of the OELs on competitiveness are estimated to be relatively modest. Only a very limited number of companies interviewed mentioned that the introduction of an EU OEL could have a moderate or even significant impact. With regard to research and development (R&D) expenditures, even if the estimates of the costs arising from the implementation of the different OELs represent a relatively small percentage of overall turnover, they still represent an increase in costs compared to the current situation, which may slightly put the R&D expenditures under pressure.

As no closures have been estimated for any of the OELs suggested in this impact assessment, it is likely that there would be low or very limited impacts on workers in terms of employment. With regard to environmental aspects, the impact of setting an OEL for acrylonitrile should also be very limited. People living close to acrylonitrile productions are indeed exposed to very low levels of acrylonitrile in the air and the introduction of an EU-wide OEL should not lead to higher levels. In addition to that, the overwhelming majority of the companies dealing with acrylonitrile already uses waste water treatments to avoid any contaminations by water.[54]

Setting an OEL of 2 mg/m³ or above would have very limited benefits for the workers and their families[55] and no benefits for the companies and the public sector. The benefits associated with an OEL of 1 mg/m³ or 0.5 mg/m³ would be exactly the same for the workers and their families as well as for the companies. The benefits for the public sector associated with an OEL of 0.5 mg/m³ would be slightly higher than with an OEL of 1 mg/m³.

Administrative costs[56] for Member States will depend on whether they already have a national OEL lower or equal to the proposed EU OEL for acrylonitrile. As mentioned in the table below, all Member States except Latvia would have to revise their national OEL in the event of option 2 or 3. According to the estimates, administrative costs would be of 50,000€ per Member State. In the event of option 4, only Latvia, Poland and Czech Republic would not need to transpose the new EU OEL.

Table 7: Multi-criteria analysis on acrylonitrile (all impacts over 60 years and additional to the baseline)

Impact	Stakeholders affected	OEL options		
		Option 2 0.5 mg/m³	Option 3 1 mg/m³ (ACSH)	Option 4 2 mg/m³
Economic impacts				
Compliance costs (one-off and recurrent)	Companies	€146,000,000	€28,000,000	€280,000
Compliance costs (one-off)*	Companies	€132,000,000	€30,000,000	€7,800,000
Compliance costs (recurrent)*	Companies	€13,300,000	-€2,000,000	-€7,500,000
Compliance costs as a percentage of turnover for an average company	Companies	0.02%-0.12% depending company size and current exposure level	0.02%-0.07% depending company size and current exposure level	Negligible
Monitoring	Companies	€0	€0	€0
Administrative costs	Public sector	€1,350,000	€1,350,000	€1,250,000

[54] European Chemicals Bureau (2004), "European Union Risk Assessment Report for Acrylonitrile. Report by Institute for Health and Consumer Protection for the European Chemicals Bureau. Available at: https://echa.europa.eu/documents/10162/22bf49d3-e951-44b8-a45a-6973d3dc62f6

[55] Workers' families can be affected in different ways (treatment costs, pain from seeing a member of the family suffering from cancer, caring duties, lost income, etc.). More information is available in Annex on the analytical methods.

[56] Administrative costs are costs that Member States will face when transposing the relevant changes into national legislation.

Avoided costs**	Companies	€ 340,000– € 1,100,000	€ 340,000–€ 1,100,000	€0–€0
Avoided costs***	Public sector	€ 27,000– € 89,000	€ 27,000– € 89,000	€0–€0
Single market: competition - No. of company closures	Companies	0	0	0
Single-market: consumers	Consumers	Limited impacts expected		
Single market: internal market****	Companies	Highest /lowest OEL from 9 to 1	Highest /lowest OEL from 9 to 2	Highest /lowest OEL from 9 to 4
International competitiveness	Companies	Limited*****	N.A.	N.A.
Specific MSs/regions - MSs that would have to change OELs	Public sector	All Member States except LV	All Member States except LV	All Member States except CZ, PL and LV
Social impacts				
No. of avoided cancer cases (brain cancer)	Workers & families	1–12	1–12	0–1
No. of avoided cases (nasal irritation)	Workers & families	73–408	73–408	28–176
Avoided costs of ill health, incl. intangible costs – METHOD 1	Workers & families	€ 440,000 - € 5,800,000	€ 440,000 - € 5,800,000	€ 110,000 - € 510,00
Avoided costs of ill health, incl. intangible costs – METHOD 2	Workers & families	€ 583,000 - € 5,430,000	€ 583,000 - € 5,430,000	€ 185,000 - € 1,050,000
Employment – Jobs lost	Workers & families	0	0	0
Employment – Social cost	Workers & families	€0	€0	€0
Environmental impacts				
Environmental releases	All	Limited impact		

Based on COWI study (2019)

** one-off and recurrent costs have been rounded in the COWI study so that the total of these two lines may not correspond to the total compliance costs.*

*** Including payments related to sick leave, absence from work, insurance premiums*

**** Including heathcare, loss of tax revenue*

***** Internal market shows the ratio of highest to lowest OEL before and after implementing the OEL option*

****** Approximatively 20% of the companies surveyed in the framework of the COWI study are of the view that the introduction of an OEL of 0.03 mg/m³ would have a moderate or significant impact on their competitiveness outside the EU. This consultation has not been carried out for the two other scenarios.*

6.2. Nickel compounds

Baseline

Around 87,500 workers in the EU are estimated to be exposed to nickel compounds in the sectors considered in this impact assessment, namely oil refineries, pigments, frits, catalysts, glass, metals and alloys, metal surface treatment[57], batteries, materials recovery and welding. Some sectors have not been considered in this impact assessment for the following reasons:

- Lack of source of information: agriculture;
- Marginal exposure or activity in the EU: mining and metal ores, manufacture of basic pharmaceutical products and pharmaceutical preparations, sewerage;
- Considered as covered by other sectors: manufacture of other inorganic base chemicals, manufacture of abrasive tools.

Lung cancer is the main cancer endpoint due to an exposure to nickel compounds. The exposure to this group of substances can also lead to other adverse health effects like pulmonary morbidity and miscarriage. Exposure to nickel compounds can also lead to sinonasal cancer. However, this endpoint is supposed to occur at concentrations above those at which lung cancer occurred, and has not been considered in this impact assessment.

Nickel compounds are not subject to authorisation according to Annex XIV of REACH. However, as indicated in Annex XVII of REACH (entry 27), the use of nickel and its compounds in jewellery (including watches) and articles that come into contact with the skin is restricted. More information about this restriction can be found in annex 10 of this impact assessment.In addition, all the nickel compounds and their mixtures cannot be supplied to the general public due to the restriction entry 28 of Annex XVII to REACH, similar to the previous case of acrylonitrile.

The exposure levels used to estimate the current and future burdens of disease vary from a sector to another[58]. It is assumed that the number of exposed workers remains constant both for the current[59] and future[60] burdens of disease. A mean latency period of 5 years for lung cancer (with a mortality rate of 80%) has been used for the calculations while it is assumed that there was no latency and a zero worker mortality rate for pulmonary morbidity and reproductive toxicity (miscarriage). The calculations enabling to estimate the number of miscarriage cases have been based on the workforce adjusted to represent those of reproductive age.

In the absence of any further action, 149 lung cancer, 718 pulmonary morbidity and 90 miscarriage cases could occur over the next 60 years, which would correspond to a total health cost between 53 and 125 million EUR.

Table 8: Baseline scenario over 60 years for nickel compounds

Types of cancer caused	**Lung cancer (quantified), nasal cancer (not quantified)**
Other adverse health effects	Pulmonary morbidity, miscarriage (quantified)
No. of exp. workers	87,488
Change exp. level	Differs by sector

[57] This sector also covers specialist metal surface treatment companies which focus upon a particular sector or product and consider themselves as being covered by NACE codes linked to these particular sectors or products rather than metal surface treatment.
[58] More information is available in Annex 6
[59] Data from 1990 to present day was used in the COWI study to develop the exposure concentrations for past exposures.
[60] Data from 2010 to present day was used in the COWI study to develop the exposure concentrations for future exposures.

Change no. of exp. workers	Past: 0% Future: 0%
Current disease burden (CDB) - no. of lung cancer cases	22
Future disease burden (FDB) - no. of lung cancer cases	149
CDB no. of other adverse health effects	Pulmonary morbidity: 135 Miscarriage: 12
FDB no. of other adverse health effects	Pulmonary morbidity: 718 Miscarriage: 90
Exp. no. of deaths FDB lung cancer	98
Exp. no. of worker deaths FDB other adverse health effects	Pulmonary morbidity: 0 Miscarriage: 0
Monetary value FDB cancer	Method 2: €43 million Method 1: €69 million
Monetary value FDB other adverse health effects	Pulmonary morbidity: • Method 1: €9 million • Method 2: €54 million Miscarriage: • Method 2: €674,000 • Method 1: €1.8 million
Based on COWI study (2019) **Workforce turns over at 5% p.a.*	

Impacts of the policy options

In its opinion on nickel and its compounds[61], RAC derives an OEL for respirable fraction of 0.005 mg/m³ (to protect against lunger cancer) and an OEL for inhalable fraction of 0.03 mg/m³ (to protect against sinonasal cancer).

RAC also recommends a skin and respiratory sensitisation notation as occupational exposure to nickel compounds may result in contact sensitisation and in rare cases also sensitisation of the respiratory tract.

In the ACSH opinion, the three Interest Groups support the notations and, after considering also feasibility and socio-economic aspects, recommend both an OEL of 0.01 mg/m³ for the respirable fraction (which would apply from January 2025, after a transitional period) and an OEL of 0.05 mg/m³ inhalable fraction (with a transitional OEL of 0.1 mg/m³ for the inhalable fraction which would apply until January 2025).

[61] See footnote 24

The multi-criteria analysis indicating impacts and stakeholders affected is summarised in the table 9 below. Unless otherwise specified, the limit value mentioned in this impact assessment is based on the inhalable fraction. Due to limited availability of relevant data, the impact of changes related to the respirable fraction could not be fully assessed.

The compliance costs represent the needed investments in RMMs to comply with the proposed OEL. Complying with an OEL of 0.03 mg/m³ would cost €11 billion to the companies over the next 60 years. These compliance costs would decrease to €4.3 billion and €947 million for an OEL of 0.05 mg/m³ [62] and 0.1 mg/m³ [63], respectively. The costs of compliance with an OEL of 0.05 mg/m³ and above represent a sustainable percentage of overall turnover, even for SMEs. Small companies operating in the oil refineries, welding and metals sectors would be the most affected and would have to invest 0.18%, 0.15% and 0.12% of their turnover over the next 60 years, respectively. However, these compliance costs would have to be entirely considered as one-off costs which would enable to invest in new RMMs. In the event of an OEL of 0.03 mg/m³, these compliance costs for companies in the oil refineries, welding and metal sectors would represent 0.37%, 0.31% and 0.31% of their turnover over the next 60 years, respectively.

To prove their compliance with an OEL, companies have to monitor the exposure of their workers. In order to comply with the OELs recommended by the ACSH, the companies could be required to also measure the exposure of the respirable fraction. The average cost of measurement for both the inhalable and respirable fractions, irrespective of the OELs level, would be of €152,000 every five-years over the next 60 years for large companies, €76,000 for medium companies and €38,000 for small ones. For small companies operating in the metal surface treatment sectors, this could represent more than 0.3% of their turnover. Therefore, it is important to take into account both the compliance and monitoring costs when assessing the potential impacts of each scenario.

As mentioned above, small companies operating in the oil refineries, welding and metals sectors would be the most affected in terms of compliance costs, as they would have to invest 0.18%, 0.15% and 0.12% (one-off costs), of their turnover in new RMMs to comply with an OEL of 0.05mg/m³, respectively. In addition to these compliance costs, these companies would also have to deal with monitoring costs representing 0.02%, 0.081% and 0.108% of their respective turnover over the next 60 years. Overall, the impact of both the compliance and monitoring costs may be higher for small companies in comparison with medium and large ones, especially as one-off costs will represent more than two thirds of the total costs. SMEs could therefore face problems when making the initial investments to comply with the new OELs. As requested by the Social Partners in the context of the two-phase consultation, socioeconomic considerations should be taken into account when adding or revising OELs. Therefore, the introduction of a transition period with a temporary higher initial value could be necessary to enable companies to anticipate the changes, gradually introduce improvements and plan the necessary investments.

The number of companies which might be forced to fully or partially cease activities varies with the level of the OEL. The stricter the OEL is, the higher the number of closures would be. At the strictest OEL of

[62] OEL recommended by the ACSH
[63] Transition OEL recommended the ACSH

0.03 mg/m³, around 90 companies (out of around 60.000) could be forced to close down, among them 80% would be small companies. The main sector impacted would be oil refineries where 61 companies (out of which 51 are small companies), representing 6% of the number of companies operating in this sector, could not be able to make the necessary investmets to comply with this OEL. With OELs of 0.05 mg/m³ and 0.1 mg/m³, this number will be much lower, or even close to zero.

In a letter[64] to the European Commission dated 7 October 2019, the Nickel Institute[65] encourages the Commission to follow the ACSH recommendation. Even if they recognised that these values (both inhalable and respirable fractions) are stringent and can be challenging, they remain committed to supporting their implementation.

As indicated in the Better Regulation Tool #21, "all compliance costs divert resources from other purposes, potentially including research and innovation". Although these compliance costs represent a small percentage of the overall turnover, they might still lead to a decrease in the R&D expenditures. This could especially be the case for catalysts and batteries sectors that would need to invest substantial amounts of money in order to position themselves in the Li-ion battery value chain. However, the companies of both these sectors should face low compliance costs compared to their turnover.

Looking beyond the EU borders, the majority of the EU competitor countries have OELs for nickel compounds that are higher than 0.05 mg/m³ (including Australia, Canada, Japan South Korea, India, Brazil, USA and China for insoluble nickel compounds). The companies located in these countries could face lower costs due to the less strict measures to protect workers from the exposure to nickel compounds. Companies which also have plants in non EU countries with less stringent legal provisions could be tempted to relocate some of their operations located in the EU in these countries. However, these companies are often large companies for which complying with a new OEL for nickel compounds should be less challenging. Furthemore and as shown in the COWI study, the EU's share in the global market for nickel metal dropped from more than 30% to less than 20% between 2008 and 2017 for the benefit of the Far East and particulary China. This seems to indicate that the level of the EU OEL will not be the only driver for the future trends for this global market.

The impacts on consumers in terms of price should be very limited. Only the metal sector, which would face higher compliance costs, could pass on a part of these costs to the price. In the event of companies passing on a part of the increase of their costs to the prices, this could have an impact on consumers which could try to buy these products from outside the EU.

The introduction of an OEL is estimated not to change the total environmental releases of nickel compounds significantly and is estimated not to have any significant environmental impact. However, two sectors in particular play a considerable role in the development of greener alternatives to fossil fuels, namely catalysts and batteries industries. Both these sectors require considerable R&D investments to satisfy, for example, the growing demand of Li-ion batteries for electric cars. The cost of

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[64] Availabe at : https://webgate.ec.testa.eu/Ares/renditionDownload/download.do?itemId=090166e5c8562c8c

[65] The Nickel Institute is the global association of leading primary nickel producers.

complying with new OELs for nickel compounds at the levels below those recommended by the ACSH (i.e. option 3) might jeopardise this development.

Setting an OEL of 0.1 mg/m³ and 0.05 mg/m³ would enable to reduce the number of lung cancer cases by about 56% and 89% over the next 60 years, the number of pulmonary morbidity cases by about 72% and 98% and the number of miscarriages by about 57% and 89%, respectively. The setting of any OELs would bring marginal benefits to the employers and the public authorities as indicated in the table 9 below. The impact on other cancer endpoints could not be quantified, resulting in an underestimation of the benefits[66].

Only five Member States, namely Bulgaria, Finland, Germany, Poland and Romania, have one single OEL for all nickel compounds. Nine Member States have no OEL at all: Cyprus, Czech Republic, Estonia, Greece, Italy, Luxembourg, Malta, Portugal and Slovenia. The fourteen remaining Member States have a mix of OELs for different nickel compounds, which can complexify the transposition of a single EU OEL for nickel compounds in their own legislation. According to the estimates, Member States with one single already existing OEL for nickel compounds should not face major administrative costs in case they would have to revise their own limit value. Member States with an existing mix of OELs would have to invest €20,000 to transpose the EU wide single OEL in their own legislation while Member States with no OEL would have to incur costs of €50,000.

Table 9: Multi-criteria analysis on nickel compounds (all impacts over 60 years and additional to the baseline)

Impact	Stakeholders affected	OEL options - inhalable		
		Option 2 0.03 mg/m³	Option 3 0.05 mg/m³ (ACSH)	Option 4 0.1 mg/m³ (ACSH transitional value)
Economic impacts				
Compliance costs (one-off and recurrent)	Companies	€10 billion	€4 billion	€886 million
Compliance costs (one-off)*	Companies	€11 billion	€4.3 billion	€947 million
Compliance costs (recurrent)*	Companies	-€1.1 billion	-€165 million	-€ 61 million
Monitoring	Companies	€2.5 billion	€2.5 billion	€2.5 billion
Compliance and monitoring costs per company	Companies	€197,000	€108,000	€55,000
Administrative costs	Public sector	€730,000	€730,000	€730,000
Avoided costs**	Companies	€4 million	€3.9 million	€2.8 million
Avoided costs***	Public sector	€2.3 million	€2.2 million	€1.5 million
Single market: competition – No. Of company closures	Companies	93	46	3
Single-market: consumers	Consumers	Limited impacts expected		
Internal market****	Companies	Highest /lowest OEL from 100 to 3	Highest /lowest OEL from 100 to 5	Highest /lowest OEL from 100 to 10

[66] Additional information about the analytical challenges leading to potential over- and underestimations is available in Annex 4

International competitiveness	Companies	Significantly negative for 38% of companies*****	NA	NA
Specific MSs/regions – MSs that would have to change OELs	Public sector	All MS except BG, DE, FI, PL, RO	All MS except BG, DE, FI, PL, RO	All MS except BG, DE, FI, PL, RO
Social impacts				
Reduction in cases – lung cancer	Workers & families	147	133	84
Reduction in cases (pulmonary morbidity)	Workers & families	712	702	517
Reduction in cases (reproductive toxicity)	Workers & families	88	80	51
Avoided costs of ill health, incl. Intangible costs (M1 and M2)	Workers & families	€79 – 97 million	€72 – 92 million	€47-64 million
Employment – Jobs lost	Workers & families	19,000	10,000	1,500
Employment – Social cost	Workers & families	€1.6 billion	€779 million	€127 million
Environmental impacts				
Environmental releases	All	No impact/limited impact		

Based on COWI study (2019)

Notes: All costs/benefits are incremental to the baseline (PV over 60 years)

** one-off and recurrent costs have been rounded in the COWI study so that the total of these two lines may not correspond to the total compliance costs.*

*** Including payments related to sick leave, absence from work, insurance premiums*

**** Including heathcare, loss of tax revenue*

*****Internal market shows the ratio of highest OEL to lowest OEL before and after implementing the OEL option.*

****** 38% of the companies surveyed in the framework of the COWI study are of the view that the introduction of an OEL of 0.03 mg/m³ would have a significant impact on their competitiveness outside the EU. This consultation has not been carried out for the two other scenarios.*

6.3. Benzene

Baseline

Approximatively 1,000,000 workers in the EU are exposed to benzene in the sectors that are included in this impact assessment, namely upstream and downstream petroleum industry, coking plants, petrochemical industry distribution of petrol, retail and petrol stations, maintenance and repair of motor vehicles, foundries, laboratories and other sectors such as paint, adhesive, traffic, fires, etc.

Benzene is not subject to authorisation according to Annex XIV of REACH. However, according to entry 5 of Annex XVII of REACH, some uses of benzene are restricted. More information about these restrictions is available in annex 10.

It is assumed for the current disease burden that the number of exposed workers in the relevant sectors has been decreasing in the past by 3%[67] per year and the exposure concentration have been decreasing by 7% per year. These past trends are partly explained by the effects of the introduction of an EU OEL for

[67] For instance, as explained in the COWI study, the number of workers exposed to benzene between 2003 and 2010 in France and between 2005 and 2014 in Finland has declined by 3.5% per year.

benzene in the CMD in 2004. Annual declines of 2% for the number of workers exposed to benzene and 0% in exposure concentrations are assumed for the future disease burden. This null trend for the future exposure concentrations is based among others on information gathered from the relevant stakeholders in the context of the COWI study. The 2% annual decrease is explained by an estimated decrease in the use of petrol due to the gradual change to electric vehicles. For the estimates of the current and future burdens of disease, a mean latency of 5 years for leukaemia and 0 years for leukocytopenia as well as a mortality rate of 80% for leukaemia and 0% for leukocytopenia have been used. Without any medical treatment, leukocytopenia can lead to weakened immune defence and increased risk of contracting infectious diseases.

The main cancer effect of benzene is leukaemia, a cancer of the blood system. Benzene also causes other hazardous effects on the bone marrow. However, due to lack of data, only leukocytopenia has been taken into account in the calculation of the burdens of disease. Other effects such as lymphocytopenia, neutrocytopenia and thrombocytopenia could not be quantified and monetised.

In the absence of any further action, up to 300 cancer cases and 237 leukocytopenia cases are estimated to occur in the coming 60 years. This has been estimated to have a health cost between 202 and 331 million euro.

Table 10: Baseline scenario over 60 years for benzene

Types of cancer caused	Leukaemia
Other adverse health effects	Leukocytopenia (quantified), lymphocytopenia, neutrocytopenia and thrombocytopenia (not quantifier)
No. of exp. workers	1,012,500
Change exp. level	Past: -7% Future: 0%
Change no. of exp. workers	Past: -3% Future: -2%
Current disease burden (CDB) - no. of cancer cases	30 in 2018
Future disease burden (FDB) - no. of cancer cases	300
FDB - no. of leukocytopenia cases	237
Exp. no. of deaths due to FDB cancer	240
Exp. no. of deaths due to FDB leukocytopenia	0
Monetary value FDB cancer	Method 1: €201 million Method 2: €329 million
Monetary value FDB other adverse health effects	Method 1: €1 million Method 2: €2 million
Based on COWI study (2019) **Workforce turns over at 5% p.a.*	

Impacts of the policy options

In its opinion on benzene[68], RAC derived an OEL of 0.05 ppm (0.16 mg/m³) under which there should be no significant residual cancer risk or other adverse effects. It also recommends a skin notation for benzene as the dermal route can be an important contributor to total benzene exposure in certain situations.

The table 11 below shows the multi-criteria analysis, summarizing both the monetised impacts as well as those that are assessed qualitatively.

Compliance cost levels for companies generally depend on the extent to which exposures are currently close to the required OELs. The higher the difference between the current exposure levels and the required OEL is, the higher the investments in RMMs will be. For the purpose of adequately assessing the economic feasibility for companies to comply with the different OEL scenarios, the annualised compliance costs in percentage of the turnover were calculated.

Overall, complying with an OEL of 0.05 ppm would cost to the employers 0.17% of their turnover every year over the next 60 years. Companies operating in the upstream petroleum sector, distribution and foundries would be the most impacted by facing higher compliance costs of about 0.24%, 0.64% and 0.29% of the turnover respectively. The average compliance costs related to an OEL of 0.2 ppm[69] across all the sectors would be of about 0.07 % of the average turnover and relatively higher for the upstream petroleum sector (0.08%), as well as the distribution (0.35%).

For the specific case of the foundry sector, employers would face relatively higher one-off compliance costs. Companies operating in this sector would have to initially invest 3.41% and 1.1% of their turnover to comply with an OEL of 0.05 ppm and 0.2 ppm, respectively. However, as mentioned in annex 3, one-off costs would represent one third of the total costs for companies. As requested by the several employers and workers' representatives in the context of the two-phase consultation, socioeconomic considerations should be taken into account when adding or revising OELs. The introduction of a transition period with a temporary higher initial OEL could enable companies to anticipate the changes, gradually introduce improvements and plan the necessary investments, softening in this way the economic impact on them.

As this industry is confronted with global competition, companies will not be able to pass on these costs to the users further down the value chain or consumers. At the strictest OEL, it is likely that companies operating in this sector would lose competitiveness, especially compared to China which represent the largest global suppliers in this sector (45% of the global market) and where companies have only to comply with an OEL of close to 2 ppm. Any other OELs equal or above the limit value recommended by the ACSH should not have any negative impacts on the competitiveness of this industry.

The Member States with the highest number of companies operating with benzene across the EU are Germany, Italy, France, Poland and Spain. More information about the share of companies by Member States in each sector is available in annex 6.

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[68] See footnote 25

[69] OEL recommended by the ACSH

The setting of a stricter EU wide OEL for benzene will have an impact on companies' cost. The companies' costs increase arising from the needed investments in RMMs in order to meet a stricter OEL could potentially weight negatively on the R&D expenditures. These impacts would depend on the level of the OEL and the sector in which the company is active.

The impact of introducing any of the envisaged OELs on employment is very limited. Only the foundry industry, which could lose global market shares at the strictest OEL, could be concerned by potential consequences on the employment. With regard to the environmental impacts due to the introduction of a stricter OEL, it is estimated that it would result in positive impact due to reduced emissions to the environment by reducing the fugitive and diffuse emissions from a number of the main sources such as upstream and downstream petroleum sectors and the coking sector.

Setting an OEL of 0.5 ppm[70] and 0.2 ppm would enable to reduce the number of leukaemia cases by about 30% and 60% over the next 60 years respectively and the number of leukocytopenia cases by about 43% and 80% respectively. Concerning the two other envisaged scenarios, they would enable to reduce further the number of leukaemia and leukocytopenia, although to a lesser extent than for the two first scenarios discussed in this paragraph. The setting of any OELs below the current OEL (baseline scenario) would bring marginal benefits to the employers and the public sector as indicated in the table 11 below. A number of non-cancer health endpoints could not be quantified, resulting in an underestimation of the benefits[71].

Although an EU wide OEL already exists for benzene, many Member States would need to revise their national OEL whatever the scenario. As indicated in the table 11, all the Member States would need to revise their OEL in the event of an EU OEL at the level of option 2. The Member States which would not need to revise their limit value for the two other scenarios are referenced in the table below. Considering that all Member States have already an OEL for benzene, the cost of transposing a revised OEL would be lower compared to the costs of transposing a new OEL. This cost has been estimated to €10,000 per Member State that would have to revise the national OEL.

Table 11: Multi-criteria analysis on benzene (all impacts over 60 years and additional to the baseline)

[70] Transition OEL recommended by the ACSH

[71] Additional information about the analytical challenges leading to potential over- and underestimations is available at Annex 4

Impact	Stakeholders affected	OEL options		
		Option 2 0.05 ppm	Option 3 0.2 ppm (ACSH)	Option 4 0.5 ppm (ACSH transitional value)
Economic impacts				
Compliance costs (one-off and recurrent)	Companies	€23,526 million	€7,610 million	€884 million
Compliance costs (one-off)	Companies	€11,329 million	2,461 million	€740 million
Compliance costs (recurrent)	Companies	€12,197 million	5,149 million	144 million
Annualised compliance costs in % of turnover*	Companies	0.17%	0.07%	0.01%
Administrative costs	Public sector	€0.3 million	€0.3 million	€0.3 million
Avoided costs**	Companies	€3 million	€2 million	€1 million
Avoided costs***	Public sector	€3.8 million	€2.5 million	€1.2 million
Single market: competition	No. of company closures	The foundry sector could see closures	No closures	No closures
Single-market: consumers	Consumers	Limited impacts expected - small price increase for fuels		
Single market: internal market	Companies	Limited impacts expected as the currently even competition between EU companies will continue. Only a few Member States (MS) have OELVs lower than current EU value and will face lower costs.		
International competitiveness	Companies	Limited impacts - only foundries could face lower competitiveness	No impacts	No impacts
Specific MSs/regions	MSs that would have to change OELs	All MS	All MS except NL	All MS except five MS****
Social impacts				
Reduction in cases (leukaemia cancer)	Workers & families	281	182	88
Reduction in cases (leukocytopenia)	Workers & families	233	189	103
Avoided costs of ill health, incl. intangible costs*****	Workers & families	€186 - 305 million	€121 - 198 million	€59 - 96 million
Employment	Jobs lost	Few	0	0
	Social cost	No quantification	€0	€0
Environmental impacts				
Environmental releases	Environment	Small positive impact of reduced fugitive and diffuse emissions		
Recycling – loss of business	Recycling companies	No impact expected		

Notes: All costs/benefits are incremental to the baseline (PV over 60 years).
** Simple average of annualised compliance in % of turnover for all affected sectors*
*** Including payments related to sick leave, absence from work, insurance premiums*
**** Including heathcare, loss of tax revenue*
*****Denmark, Estonia, Germany and Sweden have an occupational exposure limit (OEL) of 0.5/0.6 and the Netherlands of 0.2.*
****** Values relate to the two methods, method 1 and method 2*

7. HOW DO THE OPTIONS COMPARE?

The main objective is to balance health considerations against economic impacts, by proposing OELs that are still economically feasible while protecting a maximum number of workers.

This impact assessment assessed the different OEL levels without any transitional period. However, the ACSH identified sectors that might find it initially difficult to comply with the OEL proposed, and thus suggested to include transitional periods. The duration of these periods was established by the governments, workers and employers, as they have the expert knowledge about technological development in different sectors. It is assumed that these transitional periods are necessary for companies to develop their production processes to be able to comply with the OELs proposed. They should attenuate short-term negative impacts, as the necessary investments in protective measures would be spread over a longer period of time.

The aim is therefore to ensure a balanced approach and to prevent industries from closures or severe disadvantages in particular Member States due to e.g. adopting the most stringent OELs while providing an adequate protection of the workers at the EU level.

The comparison tables used to compare the different options against the baseline scenario in terms of effectiveness, efficiency and coherence apply the following ranking symbols: '0' – baseline, '≈' – similar to baseline, '+' more efficient/effective or coherent than baseline; '++' – much more efficient/effective or coherent than baseline; '-' – less efficient/effective or coherent than baseline; '- -' – much less efficient/effective or coherent than baseline.

With regard to the effectiveness, the options are analysed among others from the perspective of the prevention of deaths and other adverse health effects.

With regard to the efficiency, the options are analysed among others on the basis of how balanced they will be between adequate protection of workers at the EU level and prevention of closures and other severe disadvantages for the industries. The efficiency is also analysed from the perspective of the costs/benefits ratios. However, although an option has the best costs/benefits ratio, it does not automatically mean that the protection it will bring to workers will be considered as sufficiently adequate or that the resulting costs for businesses will be disproportionate.

With regard to the coherence, the options are analysed on the basis of how coherent they are with other EU policies (including the Charter for Fundamental Rights, the EU Pillar of Social Rights, the Europe's Beating Cancer Plan and REACH). Coherence with general EU priorities and policies, as well as with the Charter of Fundamental Rights, goes hand in hand with the level of the OELs. The lower the OEL, the more protective for workers' health. Furthermore, coherence will be also based on to what extent the opinion of the ACSH has been taken into account. Indeed, as laid down in the Council decision[72] setting up an ACSH, this Committee "*shall have the task of assisting the Commission in the preparation, implementation and evaluation of activities, in the fields of safety and health at work*".

Acrylonitrile

[72] OJ C 218, 13.9.2003, p. 1-4

With regard to effectiveness, options 2 and 3 will have the same impact on prevention of deaths and other adverse health effects compared to the baseline and the other options. Option 4 brings less benefits compared to options 2 and 3.

With regard to efficiency, all the options except option 1 have a costs/benefits ratio higher than 1. Option 4 has the lowest costs/benefits ratio, followed by option 3. Option 2 has a relatively high costs/benefits ratio compared to the previous two. However and as mentioned in introduction of this Chapter, the aim is to ensure a balanced approach between providing an adequate protection of workers at the EU level while preventing industries from closures or severe disadvantages. By recommending OELs and transitional measures through scientific, technical and socioeconomic discussion, the tri-partite ACSH is probably the best guarantee of such a balanced approach. Therefore, although all the options - except the baseline scenario - have costs/benefits ratios higher than 1, option 3 is considered as representing the best the balance between the adequate protection of workers and bearable costs for the companies. Nevertheless, as unanimously agreed by the ACSH, this balance would require a transition period of 4-years to make sure that companies could make the necessary investments.

With regard to coherence, establishing an OEL following options 2 and 3 also increases the coherence of the CMD with other EU policy objectives, including the Charter for Fundamental Rights, the EU Pillar of Social Rights and the Europe's Beating Cancer Plan. It increases complementarity with REACH, as outlined in section 4. It will also provide legal clarity and a common reference point that can be used as a practical tool by employers (particularly important for SMEs), workers and enforcers to assess compliance with the general CMD requirements, and will also contribute to a level-playing field for businesses across the EU (see section 3). For the specific case of acrylonitrile, the strictest OEL (option 2) does not bring more benefits to workers and their families and to employers than the ACSH's recommended OEL. Based on the criteria explained above, option 3 is the most coherent as it ensures the same coherence with the other EU policies as option 2 while being coherent with the opinion of the ACSH.

Option 3, with a STEL of 4 mg/m³ (1.8 ppm), a skin notation, and with a 4-years transitional period starting from the entry into force of the new Directive is therefore the preferred option.

Table 12: Comparison of options for acrylonitrile (mg/m³)

Criteria	**Option 1:** Baseline	**Option 2:** 0.5	**Option 3:** 1 (ACSH)	**Option 4:** 2
Effectiveness	0	++	++	+
Efficiency	0	--	+	-
Coherence	0	+	++	+

Nickel compounds

With regard to the effectiveness, option 2 and 3 would enable to drastically reduce the risks of work-related cancer and non-cancer diseases. Option 4 would result in a substantial reduction of the number of lung cancer, pulmonary morbidity and miscarriage cases.

With regard to the efficiency, the costs outweight the benefits for all the envisaged options, except option 1. If option 4 has the lowest costs/benefits ratio, costs associated with option 3 are much lower than those that would result from adopting option 2. Furthemore, all the Interest Groups in their ACSH opinion[73] strongly recommended the Commission to adopt a revised OEL, with a preference for option 3. This option will ensure a balanced approach between adequate protection of workers at the EU level and prevention of closures and other severe disadvantages for the industries. However, a transition at the level of option 4 has been considered as necessary to enable companies to more swiftly make the necessary investments for the purpose of reaching such a level of workers' protection. For all these reasons, option 3 could be seen as an medium-term objective with a transitional value at the level of option 4. Option 2 is considered as less efficient.

With regard to coherence, option 2 would be the most coherent with other EU policy objectives, including the Charter for Fundamental Rights and the EU Pillar of Social Rights, followed by option 3 and option 4. All the options increase complementary with REACH, as outlined in section 4. Taking into account the opinion of the ACSH (option 3 with a transition period at the level of option 4) increases also coherence as mentioned in introduction of this Chapter. Furthermore, as mentioned in the ACSH opinion, nickel compounds and chromium VI compounds are frequently occurring in the same sectors and, often, in the same processes. Therefore, aligning the measures for nickel compounds to those for chromium VI adopted in the context of the first revision of the CMD and that will apply in January 2025 would bring more coherence, both in terms of investments for companies and between the updates of the CMD.

Option 3 (0.05 mg/m³ - inhalable fraction), with a corresponding OEL for respirable fraction of 0.01 mg/m³, a skin and respiratory sensitisation notation, and with a transitional value until the 17th January 2025 included at the level of option 4 (0.1 mg/m³ - inhalable fraction), is the preferred option.

Table 13: Comparison of options for nickel compounds (mg/m³ - inhalable fraction)

Criteria	**Option 1:** Baseline	**Option 2:** 0.03	**Option 3:** 0.05 (ACSH)	**Option 4:** 0.1 (ACSH transition value)
Effectiveness	0	++	++	+
Efficiency	0	--	+	+
Coherence	0	+	++	+

Benzene

With regard to the effectiveness, option 2 will have the most positive impact on prevention of occupational exposure-related leukaemia and leukocytopenia compared to the baseline scenario.

[73] In their opinion Doc. 105619, the ACSH strongly recommends the Commission to adopt as soon as possible a revised BOEL for this substance under Directive 2004/37/EC.

However, any other envisaged OELs would significantly reduce the number of leukaemia and leukocytopenia cases..

With regard to the efficiency, even if an EU-wide OEL for benzene is already set in the CMD, all the Interest Groups in their ACSH opinion[74] strongly recommended the Commission to adopt a revised limit value. Option 3 has been considered as the most balanced option between adequate protection of workers at the EU level and prevention of closures and other severe disadvantages for the industries. However, the ACSH considered as important to foresee a transitional value at the level of option 4 from 2 up to 4 years after the entry into force of the Directive in order to give enough time to the companies to make the needed investments. Option 4 has the lowest costs/benefits ratio, followed by option 3. Option 2 is the less efficient option with much higher compliance costs than options 3 and 4. All these options have a costs/benefits ratio higher than 1.

With regard to coherence, option 2 will ensure the highest coherence of the CMD with other EU policy objectives, including the Charter for fundamental rights and the EU pillar of Social Rights, followed by option 3 and option 4. All the options increase complementary with REACH, as outlined in section 4. Coherence also depends on to what extent the opinion of the ACSH is taken into account, as explained in introduction of this Chapter., The ACSH agreed on an OEL at the level of option 3 as well as a transitional value at the level of option 4 which would enable companies to make the necessary investments.

Option 3, with transitional value at the level of option 4 from two up to four years starting from the entry into force of the new Directive and the confirmation of the skin notation, is therefore the preferred option.

Table 14: comparison of options for benzene (ppm)

Criteria	**Option 1:** Baseline	**Option 2:** 0.05	**Option 3:** 0.2 (ACSH)	**Option 4:** 0.5 (ACSH transition value)
Effectiveness	0	++	+	+
Efficiency	0	--	+	+
Coherence	0	+	++	+

8. Preferred options

8.1. Summary of the preferred options

It has been shown in the previous sections that the impacts of the considered measures for the protection of workers vary significantly for the different substances assessed in this report.The table below summarises the preferred options.

[74] In their opinion Doc. 105619, the ACSH strongly recommends the Commission to adopt as soon as possible a revised BOEL for this substance under Directive 2004/37/EC.

Table 15: Summary of the preferred options, by assessment criteria

Name of chemical agent	Retained option OEL (8h-TWA) and notation
Acrylonitrile	*8TWA:* 1 mg/m³ (0.45 ppm) *(4 years transition period*)* *STEL:* 4 mg/m³ (1.8 ppm) *(4 years transition period*)* -------------------------------- Skin
Nickel compounds	0.01 mg/m³ (respirable fraction)** 0.05 mg/m³ (inhalable fraction)** 0.1 mg/m³ (inhalable fraction – *transition period until 17th January 2025 included)* -------------------------------- Skin and respiratory sensitisation
Benzene	0.2 ppm (4 years transition period*) 0.5 ppm *(From 2 years up to 4 years after entry into force of the Directive amending the CMD)* -------------------------------- Skin

**From the date of entry into force of the Directive amending the CMD*
***The limit values for the respirable and inhalable fractions shall apply from 18th January 2025. Until then, a limit value for the inhalable fraction of 0.1 mg/m³ shall apply while no limit value for the respirable fraction shall apply.*

8.2. Overall impact of the package or preferred options

Although the recent coronavirus pandemic is expected to have substantial socioeconomic consequences, it is still too early to assess with any degree of certitude the magnitude of these impacts on the business, especially at the sectoral level. According to International Monetary Fund's (IMF) World Economic Outlook of April 2020[75], the EU-27 Gross Domestic Product (GDP) growth could decrease from 7.1% in 2020 compared to 2019 and could rebound to 4.7% in 2021. However, IMF mentions that "*there is considerable uncertainty about what the economic landscape will look like when we emerge from this lockdown*". Given the large degree of uncertainty, these impacts have not been included in the impact analysis below.

8.2.1. Impact on workers

The retained option package for the three substances or groups of substances considered in this impact assessment (henceforth "the preferred option") should result in benefits in terms of avoided work-related cases of cancer and other serious illness, and related monetised health benefits including avoidance of intangible costs such as the reduced quality of life, the suffering of the workers and their family, the pain, etc.

[75] https://www.imf.org/external/pubs/ft/weo/2020/01/weodata/index.aspx

This impact assessment is limited to assessing the most sensitive cancer endpoint and the most sensitive other adverse health effects for each substance. Nevertheless, the chemical agents under consideration pose a range of other occupational hazards for which the available data is not sufficient to estimate the magnitude of the global related benefits for workers. As a result, and taking into account general estimates of costs related to these diseases, benefits for workers and society are likely underestimated.

The greatest assessable benefits are expected in relation to nickel compounds and benzene. The retained option would indeed result in:

- Acrylonitrile: up to 12 brain cancer cases, 408 nasal irritation cases prevented and a monetised health benefit of €440,000-€5,800,000.
- Nickel compounds: 133 lung cancer cases, 702 pulmonary morbidity cases and 80 miscarriage cases prevented, and a monetised health benefit of €72-92 million.
- Benzene: 182 cases of leukaemia and 189 cases of leukocytopenia prevented, and a monetised health benefit of €121-198 million.

The costs and benefits resulting from the combination of several OELs for one substance have not been assessed in the COWI study. For that reason, the benefits mentioned above are those calculated for the preferred option for each substance without any transition measures. However, it is reasonable to consider that accompanying an OEL with transitional measures would have limited impacts on the benefits and relatively higher impacts on costs. It is all the more true that the duration of these transitional measures will be limited and it is likely that some companies have already started to make the necessary investments in anticipation of the new or more stringent OELs to come.

8.2.2. Impact on business

As regards costs incurred by enterprises for risk reduction measures, the preferred option will affect operating costs for companies which will have to put in place additional protective and preventive measures. This will be particularly the case for nickel compounds and benzene, where the total costs (compliance and monitoring costs) to industry of the retained option over the next 60 years are estimated to be about €6.5 billion and €7.61 billion respectively. Companies dealing with nickel compounds could indeed face additional monitoring costs for measuring the respirable fraction, which is not the case at the moment. However, these figures have to be put into perspective. Concerning benzene, companies, irrespective of their size or sector, will need to dedicate 0.07% of their annualised turnover each year. With regards to nickel compounds, it is estimated that the total costs per company will be of €108,000 over 60 years. In addition to that, in a letter[76] to the European Commission dated 7 October 2019, the Nickel Institute encourages the Commission to follow the ACSH recommendation. Even if the Nickel Institute recognizes that the ACSH recommended values are stringent and can be challenging, they remain committed to support their implementation by the time provided by the legislation. For these reasons, the cost per company in relative terms for both substances is expected to be sustainable, although some SMEs concerned by the use of nickel compounds might face more

[76] See footnote 64

difficulties to comply with the preferred option as discussed in the section dedicated to the impact on SMEs. In addition to that, transitional measures are foreseen for acrylonitrile, benzene and nickel compounds so that companies would have more time to make the necessary investments while already improving the protection of workers. Indeed, although the annualised cost per company is expected to be sustainable, most investments in RMMs would take place early in the 60 year period considered in the calculations. For the specific case of nickel compounds, the transition period that ends in January 2025 will ensure alignment with the measures adopted for chromium VI, since both group of substances (nickel compounds and chromium VI compounds) are frequently occurring in the same sectors and, often, in the same processes. As unanimously recommended by the ACSH[77], reducing the exposure to nickel compounds and chromium VI compounds must be coordinated and can benefit from synergies.

As discussed in section 6.3, in the case of benzene, companies operating in the foundry sector will face relatively higher one-off compliance costs compared to their turnover than in the other sectors. As shown in table 70 in annex 6, these companies are mainly located in Italy (18,7% of all the EU foundries), Germany (13,6%) and Czech Republic (12,9%).

Impact on SMEs

For nickel compounds and benzene, SMEs represent a large proportion of the relevant industries while companies using acrylonitrile are mainly large companies. For the specific case of nickel compounds, 95% of the companies are even small companies. Therefore, SMEs specificities, their limitations and particular challenges have been duly taken into account in the overall analysis presented in section 6.

Many of the RMMs required to meet the OELs involve capital expenditure, and SMEs might face higher cost of finance compared to large companies. However, the analysis has shown that in most cases, costs which will be incurred by SMEs dealing with acrylonitrile and benzene are not significant. Some SMEs concerned by the use of nickel compounds and operating in the oil refineries, welding and metals sectors might face more difficulties to comply with the preferred option. As shown in table 60 in annex 6, more than 1,000 companies dealing with nickel compounds in these three sectors are small companies while 200 are medium companies. Therefore, transition periods with higher initial values are necessary to ensure that it is possible for companies to anticipate the changes, gradually introduce improvements and plan the necessary investments.

Moreover, introduction of an OEL will only have a significant impact on companies which have not yet made the investments to protect workers either through closed systems or substitution of the substances where technically feasible.

Impact on competition and competitiveness

The preferred option would have a positive impact on competition within the internal market by decreasing competitive differences between firms operating in Member States with different national OELs and providing greater certainty concerning enforceable exposure limit across the EU. Regarding the

[77] The links to these ACSH opinions are available at the Annex II

specific case of nickel compounds, the capital expenditures required for start-ups to ensure compliance with the EU OELs could make their entry into the market more difficult.

Even if the retained option has often more stringent OELs compared to the European Union's main competitor countries, it should not have a significant impact on the external competitiveness of EU firms. The detailed assessment provided above shows indeed that in most cases additional compliance costs per firm are not significant although some SMEs operating in the oil refineries sector might face more difficulties to comply with the preferred option, as discussed above.

It has however to be noted that the foundry sector dealing with benzene, which will face relatively high one-off compliance costs with the retained option and operates in a global market, could face more difficulties. The European foundry sector currently holds a global market share around 10-15% and has to compete with China (which holds 45% of the global market), India and the USA. While India and the USA have OELs that are lower than or similar to the current EU OEL of 1 ppm[78], in China, companies have to comply with an OEL of 1.9 ppm. European companies in this sector could therefore face a greater competition due to the retained option. However, these possible impacts could not be estimated. Moreover, the preferred option has a transition period which will give more time to the companies to adjust to these changes.

It should also be noted that OELs established in the non EU countries cannot necessarily be compared to the EU limit values. OEL setting methods and the implementation of OELs differ substantially across jurisdictions as a result, for example, of different approaches to whether and how socioeconomic factors may be taken into account, differences in legal enforceability or expectations regarding compliance, use of scientific evidence and analytical method, industrial relations and roles played by industry, worker representatives, and others. As a result, caution should be exercised in making comparisons and drawing conclusions regarding values which may not be directly comparable.

8.2.3. Impact on environment

The impact of the package of the preferred options on environment depends on the substances. Setting an EU-wide OEL for acrylonitrile and nickel compounds will not lead to higher releases in the environment and have therefore no impact. With regard to benzene, lowering the existing OEL at the EU level will even reduce the fugitive or diffuse emissions in some sectors as explained in section 6. Revising the limit value at the level of the preferred option for benzene would therefore have positive impacts on the environment. The introduction of the preferred option for acrylonitrile will not lead to further installation of LEVs that might lead to increased emissions in the air. None of the potential RMMs to comply with the preferred option for acrylonitrile are expected to lead to significant changes in the releases of acrylonitrile to water. The introduction of the preferred option for nickel compounds should not significantly change the total environmental releases of nickel compounds.

In addition to the direct impacts on environment, the introduction of an OEL could also lead to indirect impacts. As mentioned in section 6, nickel compounds play a considerable role in the development of

[78] India = 0.5ppm / USA (OSHA) = 1 ppm

greener alternative to fossil fuels. The Nickel institute considers that the need for nickel and its compounds will keep growing as they support "*the development of solutions and innovations to address some of the most pressing challenges, such as energy storage and supply, sustainable, recyclable products and green transport*"[79]. The compliance costs arising from lowering the OEL to the level of the preferred option should however not have any impacts on the innovative capacity of the sectors using nickel compounds to develop these solutions and innovations.

While an EU OEL for acrylonitrile should not lead to higher releases in the environment and have therefore no significant impact, the acrylonitrile industry also has a role to play in developing greener technologies for some sectors. It is however difficult to say at this stage whether this positive impact will be significant. For example, this substance is widely used to produce high performance elastomers/rubbers, structural resins and plastics, which are essential for the automotive sector's transition to lightweight, fuel efficient and electric vehicles[80]. Acrylonitrile is also essential to produce water purification coagulants[81] and is key to produce carbon fibres used in wind turbine blades' manufacturing.

8.2.4. Impact on Member States/national authorities

Member States with established OELs at the level of the retained option will be less affected than those having higher or no OEL in place. Each multi-criteria analysis above lists, for each option, the Member States that will have to enforce a stricter OEL. More details and national OELs for all substances are provided in annex 5. The preferred option should contribute, although not significantly, to reduce the costs related to occupational diseases for social security systems. Additional administrative and enforcement costs might be incurred by enforcing authorities. These costs are not quantifiable as the granularity of Member States' reporting of enforcement activity is not sufficient to distinguish costs related to a particular OEL.

However, it is not expected for the costs to be significant. OEL enforcement will take place according to already existing mechanisms for compliance improvement and enforcement, including informal conversations with employers as well as formal correspondence and legal enforcement action.

Usually, national inspectors organise visits in companies to ensure the employers' compliance with several OSH provisions (for example, workplace transport, slips and trips, machinery safety, stress) rather than only checking the conformity with the OELs. Specific reporting would only be the case where Labour Inspectorates undertake targeted chemical carcinogen enforcement activity and OEL campaigns. Costs will therefore be generally affected by Labour Inspectorate resourcing, prioritisation and targeting. No assumption may be made that enforcement, a Member State competence, will receive (or demand) greater resourcing and priority as a result of an OEL being set.

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[79] Nickel Institute (2015), Nickel compounds – the inside story….
Available at: http://nickel-japan.com/magazine/pdf/NickelStory_EN.pdf

[80] Petrochemicals Europe, Uses and Propreties. Available at : https://www.petrochemistry.eu/sector-group/acrylonitrile/

[81] See footnote 18

At the same time, establishing OELs, and other explicit references to a given substance in the CMD brings clarity regarding legal requirements, and so facilitates the work of inspectors by providing a helpful tool for compliance checks. Setting OELs at EU level would also limit the need for national administrations to carry out the costly and burdensome necessary work for establishing those limit values at national level.

8.2.5. Impact on fundamental rights

The impact on fundamental rights is considered positive, in particular with regard article 2 (Right to life) and article 31 (Right to fair and just working conditions which respect his/her health, safety and dignity).

8.2.6. Subsidiarity, proportionality and REFIT

In view of the available scientific evidence it is necessary to establish both new OELs for a number of substances for inhalation exposures and information on other routes of exposure (e.g. dermal) which could contribute significantly to the overall body burden of the workers. The protection of workers health against risks arising from exposure to carcinogens is already covered by EU legislation, in particular by Directive 2004/37/EC (CMD), which can be amended at EU level after a two-stage consultation of the social partners. The preferred option takes into account long and intensive discussions with all stakeholders (representatives from workers' associations, representatives from employers' associations, and representatives from governments), including consideration of socioeconomic feasibility.

Updating the CMD to take account of newer scientific evidence is an effective way to ensure that preventive measures would be updated accordingly in all Member States, providing a uniform level of minimum requirements designed to guarantee a better standard of health and safety. Action taken by individual Member States in response to available technical data would risk increasing divergences between Member States with potential competition on the basis of OELs set at different levels. Business would therefore continue to compete on an uneven playing field, which would hamper the operation of the internal market. Updating the CMD therefore complies with the principle of **subsidiarity**.

The **proportionality** principle is fully respected as the preferred option is limited to setting out the limit values for three additional agents by amending Annex III to the Directive on the basis of the scientific and technical data available, as provided by Article 16 (1) of the CMD. This initiative aims to make a step forward to achieve the objectives set to improve living and working conditions of workers.

With regard to the preferred option, socio-economic and feasibility factors have been taken into account after intensive discussions with all stakeholders within the ACSH (representatives of workers' organisations, representatives of employers' organisations, and representatives of governments). It also includes measures for mitigating burdens and supporting compliance (including transition periods) which have also been discussed by the relevant stakeholders. These transitional measures contribute to the proportionality of the preferred options by ensuring a more appropriate temporal margin for businesses to adapt.

As shown above, the costs outweight the quantified benefits for all the preferred options. However, the selection of the most appropriate option cannot be done merely on the basis of a costs/benefits ratio comparison. Indeed, the main general objective of this initiative is to ensure to the workers the right to a high level of protection of their health and safety at work. This objective is in line with the European pillar of Social Rights, which enshrines workers' right to healthy, safe and well-adapted work environment, and with the upcoming Europe's Beating Cancer Plan. As mentioned in Chapter 7, the aim of this initiative is to ensure a balanced approach, i.e. to prevent industries from closures or severe economic disadvantages while providing an adequate protection of the workers at the EU level. The preferred options are considered balanced and justified in light of the accrued and longer-term benefits in terms of reducing health risks arising from workers' exposure to carcinogens and saving lives. Despite their high costs, the preferred options have the support of the key stakeholders in the area of OSH, namely the employers, employees and national governments representend within the ACSH. It also needs to be noted that, when considering the costs per company and, in particular when comparing the expected costs to the turnover of the average company, the estimated burden is overall sustainable.

Furthermore, the preferred options also offer a certain margin of flexibility to Member States. In accordance with Article 153(4) of the TFEU, setting OELs at the EU level does not prevent Member States from maintaining or introducing more stringent protective measures (i.e. lower limit values). However, Member States cannot set higher limit values than the EU OELs set in the Annex III of the CMD.

Finally, regarding the **simplification** and the efficiency improvement of the existing legislation, the preferred option eliminates the need for Member States to conduct their own scientific analysis to establish OELs for the three substances and brings clarity regarding the acceptable levels of exposure, facilitating the work of inspectors by providing a helpful tool for compliance checks. Employers also benefit from the simplification in ensuring legal compliance, particularly those operating in different Member States.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

9.1. Monitoring arrangements

The table below presents the core indicators for each operational objective and the data sources for the monitoring of the core indicators.

Table 16: Indicators and monitoring arrangements/data sources

Operational objective	Indicators	Monitoring arrangements/data sources for monitoring indicators

The reduction of occupational diseases and occupational related cancer cases in the EU	The number of occupational diseases and occupational related cancer cases in the EU	The data sources for the monitoring of this indicator are: - data that could be collected by Eurostat on occupational diseases if the results of the on-going feasibility study are positive, as well as on other non-cancer work-related health problems and illnesses in accordance with Regulation (EC) No 1338/2008[82]. - data notified by employers to the competent national authorities on cases of cancer identified in accordance with national law and/or practice as resulting from occupational exposure to a carcinogen or mutagen in accordance with Art. 14 (8) of Directive 2004/37/EC, and which may be accessed by the Commission in accordance with Article 18 of Directive 2004/37/EC. - data submitted by Member States in the national reports on the implementation of EU the OSH acquis, submitted in accordance with Art. 17a of Directive 89/391/EEC.
The reduction of costs related to occupational cancer for economic operators and for social security systems in the EU	The costs related to occupational cancer for economic operators (e.g. loss of productivity) and social security systems in the EU.	The monitoring of this indicator will require the comparison of the expected figures on the burden of occupational cancer in terms of economic loss and health care costs and the collected figures on these matters after the adoption of the revision. The productivity loss and health care costs can be established on the basis of the data on the number of occupational cancer cases and the number of occupational cancer deaths (the arrangements for the collection of the data on occupational cancer cases are described supra in this table).

A two-stage compliance assessment (transposition and conformity checks) will be carried out by the Commission for the transposition of the limit values. At workplace level, there is an obligation for employers to ensure that the exposure does not go above the limit values set out in Annex III to the Directive. The monitoring of application and enforcement will be undertaken by national authorities, in particular the national labour inspectorates. At EU level, the Committee of Senior Labour Inspectors (SLIC) informs the Commission regarding problems relating to the enforcement of Directive 2004/37/EC.

While collection of reliable data in this area is complex, the Commission and EU-OSHA are actively working on improving data quality and availability so that the actual impacts of the proposed initiative could be measured in a more accurate way and additional indicators could be developed in the future (e.g. in relation to mortality caused by occupational cancer). Ongoing projects include cooperation with national authorities on the European Occupational Diseases Statistics (EODS) data collection.

Legislative action needs to be followed up through effective implementation at the workplace. In this context, EU-OSHA has carried out a Healthy Workplaces Campaign on dangerous substances in 2018-2019 pursuing several objectives, including raising awareness of the importance of preventing risks from dangerous substances, promoting risk assessment, heightening awareness of risks to exposure to carcinogens at work or increasing knowledge of the legislative framework. Under the framework of this

[82] Regulation (EC) No 1338/2008 on Community statistics on public health and health and safety at work, OJ L 354/70, 31.12.2008

campaign, EU-OSHA has provided a broad range of tools, information and good practices that will support the implementation of this Directive.

9.2. Evaluation arrangements

In accordance with Article 17a of Directive 89/391/EEC, every five years, Member States are required to submit a report to the Commission on the practical implementation of the EU OSH Directives, including Directive 2004/37/EC. Using these reports as a basis, the Commission is required to evaluate the implementation of Directive 2004/37/EC and, to inform the European Parliament, the Council, the European Economic and Social Committee and the Advisory Committee on Safety and Health at Work of the results of this evaluation and, if necessary, of any initiatives to improve the operation of the regulatory framework.

Given the data challenges explained earlier, it is suggested to make use of the next relevant evaluation exercise, after the end of the transposition period, to define the baseline values (benchmark) that will allow assessing the effectiveness of further amendments of the CMD. Evaluation of the practical implementation of the proposed amendments could possibly be based on the following period (2023-2027).

Annex 1: Procedural information

1. Lead DG, Decide Planning/CWP references

Lead DG: Directorate-General Employment, Social Affairs and Inclusion, Unit B/3 Health and Safety.

2. Organisation and timing

A first consultation of the Occupational Safety and Health Inter-services Steering Group (OSH ISG) on the draft Impact Assessment Report (IAR) was launched on 27 February 2020 with a deadline for comments on Friday 20 March 2020. Twelve services (SG, SJ, BUDG, GROW, ENER, ENV, RTD, CNECT, EAC, SANTE, JUST, ESTAT) as well as EU-OSHA have been consulted. Most of the comments provided by the services have been addressed in the revised draft IAR. A table summarising the key comments and the way DG EMPL addressed them in the revised IAR was circulated.

A second consultation of the OSH ISG on the revised draft IAR was launched on 30 March 2020 with a deadline for comments on Tuesday 14 April 2020. This second consultation was carried out with the same services than for the first consultation. DG EMPL took most of these comments into consideration in the revised version of the draft IAR. This revised version of the draft IAR was sent to the Regulatory Scrutiny Board (RSB) on 24 April 2020.

3. Consultation of the RSB

The RSB opinions for the first three CMD amendments have been taken into account when carrying out this Impact Assessment. The draft IAR for this initiative was submitted to the RSB on 24 April 2020 and the meeting with the RSB has taken place on 27 May 2020. Following this meeting, the RSB gave a positive opinion with reservations.

The table below summarises the RSB comments as well as the revisions introduced in response to them:

RSB opinion's comments	Corresponding changes to the draft IAR
The report is not sufficiently clear how the situation would evolve without exposure limits (baseline scenario). It does not factor in trends in actual exposure and the impacts of the Directive's requirement that employers minimise workers' exposure. (comments B1 and C2)	Section 2.3. has been further developed to explain that assumptions made to asses how will the problem evolve are based both on the legal provisions contained in the CMD (including the minimisation requirements) and on other data including information gathered from stakeholders. This has also been specified in the "analytical methodology" section of Chapter 6. Further explanations aiming to underpin the choice of the assumptions for the trends in terms of exposure levels for the three substances have been added in Chapter 6 (as well as in Annex 6 for the specific case of nickel compounds).

The report does not sufficiently analyse the impacts of the various transitional periods, which it introduces only at the stage of comparing options. The report should justify the choice of durations and starting points of the proposed transitional periods for each substance when describing the options. It should clarify whether it proposes transitional periods to synchronise with equipment renewal cycles. (Comments B2 and C4)	Section 5.2 further explains why it was not possible to assess the combination of several OELs introduced by the use of transitional periods (as recommended by the ACSH) as policy options. These combinations have been recommended by the ACSH while the COWI study was already at an advanced stage so that it was not possible anymore to asses their costs and benefits. However, this section also specifies that all the transitional OELs are covered by the assessed policy options. Although the costs and benefits of the combination of OELs are not available, a paragraph has been added in section 8.2 to explain that they should have limited impacts on the benefits and relatively higher impacts on costs. Chapter 7 further explains the choice of the transition measures for all the substances, when comparing the policy options. With regard to the specific case of nickel compounds, a paragraph has been added in Chapter 7 to explain how coherent it would be to align (synchronise) the transitional measures for this substance to those agreed for chromim VI in the context of the first revision of the CMD. Chapters 6 and 8 further describe the need for a transition period for acrylonitrile.
The report does not sufficiently explain the criteria for selecting the preferred options. The relative weight of consultative processes vs. cost benefit analysis is not clear. (Comments B3 and C6)	A part of the section 1 has been edited to further explain the broad consultation that has been conducted to prioritise the three substances. Chapter 7 has been revised to further explain on the basis of which critera the efficiency, effectiveness and coherence of the policy options have been assessed. The paragraph dedicated to the efficiency further explained how both the consultative process and costs/benefits analysis are taken into consideration.
The report does not sufficiently assess the proportionality of the preferred options. (Comments B4 and C7)	The paragraphs in Chapter 8 dedicated to the proportionality have been further improved, including by explaining the role of the tri-partite stakeholders when considering limit values that would ensure a balanced and adequate protection of the workers at the EU level and how this contribute to have proportionate preferred options.

The report could explain how the Occupational Safety and Health evaluation and the conclusions of the REACH REFIT evaluation have fed into this impact assessment. Where relevant, it should explicitly refer to evaluation findings in the problem definition. (Comment C1)	Some paragraphs have been added in section 1 to explain to what extent these evaluations go hand in hand with this initiative and this IAR.
The report should clearly distinguish between the problems for Acrylonitrile and Nickel compounds (for which EU OELs do not exist) and Benzene (which has an EU OEL). For benzene, the report should better explain how the existing OEL has worked and why there is a need to revise it. Similarly, the report should distinguish arguments on subsidiarity that apply to the new OELs (acrylonitrile, nickel compounds) and revised ones (benzene). (Comment C3)	Section 2.2 has been edited to explain what did the existing EU OEL for benzene bring compared to a scenario with no existing EU OEL. Section 3.2 further distinguishes the necessity and added value of EU action for acrylonitrile and nickel compounds (substances without any EU OEL) and benzene (substance with an existing EU OEL).
The cost analysis should better reflect what investments are regular equipment renewal, which is part of the baseline, as opposed to additional investment to comply with the new OELs. Comment (C5)	Two lines have been added in tables 7, 9 and 11 to split in two the compliance costs: one-off and recurrent compliance costs. Furthermore, the section “impacts of the policy options” dedicated to acrylonitrile has been edited to better refer to this distinction between one-off and recurrent costs. A footnote has been added in tables 7 and 9 to clarify that one-off and recurrent costs have been rounded in the COWI study so that the total of these two lines may not correspond to the total compliance costs.

4. EVIDENCE, SOURCES AND QUALITY

Risk Assessment Committee’s Opinions

The assessment of health effects of the carcinogens subject to this proposal is based on the relevant scientific expertise from ECHA’s Committee for Risk Assessment (RAC).

RAC prepares the opinions of the European Chemicals Agency (ECHA) related to the risks of substances to human health and the environment. RAC examines among others the proposals for harmonised classification and labelling, evaluates whether the proposed restriction on manufacture, placing on the market or use of a substance is appropriate in reducing the risk to human health and the environment, and assesses the applications for authorisation of chemicals. Moreover, opinions from RAC also support

Union regulatory activity in the field of occupational safety and health. More information about what this committee does can be found on the website of ECHA[83].

RAC develops high quality comparative analytical knowledge and ensures that Commission proposals, decisions and policy relating to the protection of workers' health and safety are based on sound scientific evidence. Based on a Service Level Agreement (SLA) signed by DG EMPL and ECHA, this Committee assists the Commission delivering scientific evaluations, upon request, on the toxicological profiles of each of the selected priority chemical substances in relation to their adverse health effects on workers. These scientific evaluations shall, where appropriate, include proposals for Occupational Exposure Limit values (OELs), biological limit values/biological guidance values and/or notations. Based on such opinions, the Commission will propose occupational exposure limits for the protection of workers from chemical risks, to be set at Union level pursuant to Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council.

Members of RAC are highly qualified, specialized, independent experts selected on the basis of objective criteria. They provide the Commission with Recommendations and Opinions that are helpful for the development of EU policy on workers protection.

For the purpose of this initiative, the Commission services have used the relevant chemical agent-related RAC opinions which are summarised in the following table:

Table 17: Summary of the RAC opinions

Chemical	8 hrs TWA[84]	STEL 15'	Notations
Acrylonitrile[85]	1 mg/m³ (0.45 ppm)	4 mg/m³ (1.8 ppm)	Skin
Nickel and its compounds[86]	0.005 mg/m³[87] 0.03 mg/m³	none	Sensitisation
Benzene[88]	0.05 ppm (0.16 mg/m³)	none	Skin

Studies performed by external consultants

The Commission launched a call for tender on 9 May 2018 an open call for tender[89] in order to carry out an assessment of the social, economic and environmental impacts of a number of policy options concerning the protection of workers health from risks arising from possible exposure to a certain number of substances at the workplace, including acrylonitrile, nickel compounds and benzene.

[83] https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment
[84] Inhalable fraction unless otherwise specified
[85] See footnote 23
[86] See footnote 24
[87] Respirable fraction
[88] See footnote 25
[89] Call for Tender documents available at: https://etendering.ted.europa.eu/cft/cft-display.html?cftId=3559

The contract started on 3 September 2018 and lasted 11 months. The outcome of this study provides the main basis for this Staff Working Document and is summarised in the relevant sections of this document.

Annex 2: Stakeholder consultation

The following consultation activites have been performed :

1. *<u>Social Partners Consultation</u>*: as requested by the TFEU Article 154, a formal two-stage consultation of the social partners at EU level is required prior to submitting proposals in the social policy field. Such a two-stage consultation has been performed in 2017. The first phase of social partners' consultation closed on 30 September 2017 where 3 substances have been identified for this initiative. The second phase consultation closed on 22 December 2017 and confirmed these 3 substances as to be addressed in this initiative. More information about these two-stage consultation is provided below in this annex 2.
2. *<u>Tripartite consultation (ACSH)</u>*: the tripartite Advisory Committee on Safety and Health (ACSH), composed of three full members per Member State, representing national governments, workers' and employers' organisations, is consulted on regular basis. It gives, taking into account the input of the RAC as well as socio-economic and feasibility factors, opinions which are used to prepare the Commission's proposal. More information about this tripartite consultation is provided below in this annex 2.
3. *<u>Consultation of other stakeholders</u>* (e.g. industry of employees associations specifically concerned): These consultations have been carried out in the context of the COWI study in order to collect detailed information on the potential impacts of establishing or revising OELs under the CMD that is not available in published literature and internet searches.

In line with the previous three amendments of the CMD, no *<u>public consultation</u>* on this initiative has been launched for the following reasons:

- A broad consultation of various stakeholders, social partners and Member States' competent authorities has been carried out in view of this initiative.
- This initiative concerns a very technical topic for which the general public does not have sufficient expertise. For that reason, a more targeted consultation has been considered as a more proportionate approach.
- In the context of the scientific opinions carried out by RAC, stakeholders were allowed to express their views and concerns in the early phases of developing the scientific reports on occupational exposure limits for acrylonitrile, nickel compounds and benzene.

Due to the exceptional circumstances related to the coronavirus pandemic and the delay caused in the legislative procedure concerning this initiative, no inception impact assessment has been published.

1. Social Partners Consultation

1.1. Results of the first phase of the Social Partners consultation.

The first phase of Social Partners consultation closed on 30 September 2017.

The Commission consulted the Social Partners among others on the establishment and/or revision of further binding OELs in Annex III to the CMD.

Following a process described in more detail in annex 8 of this report, the Commission identified a first proposed list of priority substances for a subsequent amendment revision of the CMD in the first phase consultation document[90], as follows:

a) Nickel compounds under the scope of the CMD
b) Acrylonitrile [CAS No 107-13-1]
c) Benzene [CAS No 71-43-2]

Workers' organisations

Three trade unions replied to the consultation: the European Trade Union Confederation (ETUC), European Confederation of Independent Trade Unions (CESI), European Federation of Building and Woodworkers (EFBWW). They all acknowledged the importance of the existing legislation and a need for further action.

The workers' organisations agreed, broadly, with the issues described in the consultation document and confirmed the importance they attach to protecting workers from the health risks associated with exposure to carcinogens and mutagens.

Concerning the approach regarding the fourth amendment, ETUC and EFBWW agree with the list of 3 priority substances identified by the Commission. CESI considers that the latest available data need to be used when revising the CMD.

As regards the other substances to be added to Annex III, while CESI suggests that they should be identified on the basis of sound and independent scientific research, ETUC and EFBWW insist that the target of binding OELs for 50 substances has to be achieved by 2020. ETUC has proposed a priority list of such substances. After 2020, the process of setting OELs should continue on a dynamic way in order to include most of the substances at the workplace. In the enclosed annex of its priority substances list ETUC has indicated it as a candidate for the fourth amendment.

With regard to Annex I to the CMD, ETUC considered important to include all processes generated substances for which IARC monographs are available.

CESI and EFBWW considered that legislative initiatives should be complemented by other measures, for example, fostering preventative health-oriented behaviour and information on best available technology.

The workers do not want to enter into negotiations under Article 155 TFEU concerning the third and fourth amendment of the CMD and urge the Commission to make progress on this.

Employers' organisations

[90] See footnote 16

Four employers' organisations replied to the consultation: BusinessEurope, the European Association of Craft Small and Medium-sized Enterprises (UEAPME), the European Chemical Employers Group (ECEG) and the Council of European Employers of the Metal, Engineering and Technology-based industries (CEEMET).

They supported the objective to effectively protect workers from occupational cancer, including by setting OELs at EU level. However, they also raised some concerns about the approach taken when setting such limit values.

The employers in principle supported further revisions of the CMD, subject to certain conditions. In their opinion, binding OELs should be set for priority substances only. The process of OELs setting should be based on sound scientific evidence, technical and economic feasibility, socioeconomic impact assessment and opinion of the tripartite ACSH. While employers considered that the Commission's criteria for prioritising substances are relevant, they suggested that the criteria of technical and economic feasibility should also be included. BusinessEurope and CEEMET emphasized that proposing a series of substances on the basis of unofficial lists should be avoided, as should setting an arbitrary numerical target of additional binding OELs without clear criteria of prioritisation. UEAPME and CEEMET stressed the need to assess impact on SMEs and consider sectoral differences. Employers also highlighted a need to ensure coherence with other EU chemicals legislation and suggested that guides, examples of good practice and other tools can assist in implementing this Directive.

For subsequent amendments BusinessEurope stressed that inclusion of specific substances should depend on whether they meet the conditions / criteria mentioned above and whether the preparatory work has been completed. ECEG and CEEMET supported the overall process for developing and adopting binding OELs as long as the above criteria and processes are correctly applied. UEAPME, noted that without having seen concrete proposals for OELs it is not possible to take a complete position. They further suggested that the latest available data need to be used when revising the CMD (supported by CEEMET) and that too restrictive OELs could be very burdensome for employers leading to a risk of non-compliance.

The employers do not want to enter into negotiations under Article 155 TFEU as the existing preparatory procedures already involve Social Partners. Although, they are open to discussing in an informal way relevant issues.

1.2. Results of the second phase of the Social Partners consultation

The Commission launched a second phase consultation of the Social Partners which closed on 22 December 2017. In this second phase consultation, the Commission indicated among others that a first candidate list of the following substances is given consideration:

- Nickel compounds that are carcinogens as defined in the Directive
- Acrylonitrile [CAS No 107-13-1]
- Benzene [CAS No 71-43-2]

- Diesel Engine Exhaust Emissions (DEEE). At least two approaches are being explored – to address this mixture as a process generated substance or to take a component-specific approach[91].

Workers' organisations

Three workers' organisations replied to the second phase consultation: the European Public Service Union (EPSU), the European Trade Union Confederation (ETUC) and the European Federation of Building and Woodworkers (EFBWW). They all recognised the importance of further improving the existing legislative framework in line with the proposed Commission action and beyond.

Concerning Annex III, the workers' organisations agree that the first candidate list for the fourth batch is appropriate, as it includes substances that are among priority carcinogens. However, they underline that the list must be extended to reach the objective of setting 50 OEL by 2020. As regards the setting of OEL, ETUC points the need to define a consistent and more transparent methodology, asking the Commission to consider its priority substances list. EFBWW underlines that the OELs should be health based only, while ETUC stresses that socioeconomic considerations might be relevant for adapting Annex III, although not for Annex I. As a final point, EPSU considers that including some cytotoxic drugs in Annex III would be possible, but other actions are needed to tackle the exposure to these substances.

The workers' organisations agree that the amendment of the CMD should be part of a global strategy to prevent occupational cancer in Europe and urge the Commission to adopt a roadmap combining legislative initiatives (e.g. the revision of the Asbestos Directive and the revision of the Optical Radiation Directive) with non-legislative actions and mainstreaming work-related cancer prevention in other EU policies.

The workers' organisations do not want to launch a negotiation procedure pursuant to Article 155 TFEU.

Employers' organisations

Four employers' organisations replied to the second phase consultation: BusinessEurope, the European Association of Craft Small and Medium-sized Enterprises (UEAPME), the European Chemical Employers Group (ECEG) and the Council of European Employers of the Metal, Engineering and Technology-based industries (CEEMET). They confirmed their support to actions aiming to effectively protect workers from occupational cancer, including the setting OELs at EU level but underlined the need to ensure values that are proportionate and feasible.

The employers' organisations support the procedures for considering substances and setting OEL, underlining the need that they are based on the latest scientific information, proportionate and measurable and highlighting the importance of the tripartite system. UEAPME and CEEMET point that

[91] As indicated in Annex 9, after the closing of this two-stage consultation, the co-legislators, in the framework of the second reivision of the Directive 2004/37/EC, added DEEE in the annex I of the CMD and set an corresponding OEL in the Annex III, thereby pre-empting the preparatory work of the European Commission. Therefore, as DEEE was addressed in the second revision of the CMD, there was no need anymore to consider it in the framework of the fourth revision of the CMD.

the limit values have to be set in a way which reduces workers exposure whilst still allowing SMEs to comply. CEEMET also proposes transitional measures where the new OEL will adversely affect industry and points that an arbitrary target of the addition of 50 new exposure limits should not be set, as OEL should only be proposed on an evidence-based approach and not in line with the precautionary principle.

Regarding the scientific body to provide information for the setting of OELs, BusinessEurope thinks that there should be a thorough assessment before any decision is taken, while CEEMET believes that SCOEL should be the one setting the limit values.

BusinessEurope encourages the Commission to continue its preparatory work and consultations with the ACSH regarding the candidate list of substances for the fourth batch.

Finally, ECEG, BusinessEurope and CEEMET stress the importance of other actions to achieve worker protection in addition to legislation, such as guidance documents, best practices, voluntary product stewardship programmes by companies and sectors, or social partner agreements.

The employers' organisations do not want to engage into negotiations under Article 155 TFEU.

2. Consultation of the ACSH/WPC

The Advisory Committee on Safety and Health at Work (ACSH) has adopted opinions for acrylonitrile, nickel compounds and benzene, in the context of the fourth amendment of the CMD.

The ACSH is proposing as possible approaches for these chemicals one or several binding OELs with additional notations for all of them.

The opinions for all substances adopted by the ACSH are summarised below.

Acrylonitrile

The ACSH adopted its opinion for acrylonitrile[92] on 4 June 2019, putting forward the following values and transition measures:

- An 8 hours TWA limit value of 1 mg/m³ (0.45 ppm) and a STEL of 4 mg/m³ (1.8 ppm) that would apply after a four year transition period starting from the entry into force of the new Directive.

The ACSH strongly recommended the Commission to adopt as soon as possible a binding OEL for this substance under Directive 2004/37/EC.

The ACSH also agreed on the Biological Limit Value (BLV) as proposed by RAC[93] but note that, at present, BLVs are not proposed under the CMD. It suggested that this BLV is taken into consideration when developing the guidance on the practical use of biomonitoring.

[92] Available at: https://circabc.europa.eu/ui/group/c9ba7ef7-03a1-41be-b69d-4ab203c3d93f/library/d1f997b8-8c0a-418b-8daa-9170d5ad8ec8/details

[93] 60 µg CEV/L blood (erythrocyte fraction of whole blood)

Nickel compounds

The ACSH adopted its opinion for nickel compounds[94] on 4 June 2019, putting forward the following values and transition measures:

- Two 8 hours TWA limit values of 0.01 mg/m³ (respirable fraction) and 0.05 mg/m³ (inhalable fraction) that would apply from 17th January 2025. Until then, an 8 hours TWA limit value of 0.1 mg/m³ (inhalable fraction) would apply.
- The ACSH indeed recommended that the date of application ot the OELs for nickel compounds should ensure alignment with the date of application of the OEL for chromium (VI) compounds adopted in Directive 2017/2398/EU[95]. Both groups of substances (nickel compounds and chromium VI compounds) are indeed frequently occurring in the same sectors and, often, in the same processes. The ACSH is therefore of the opinion that actions to reduce the exposure to chromium VI and nickel compounds must be coordinated and can benefit from synergies.

The ACSH also added that in a limited number of sectors or processes, including specifically smelting, refineries and welding, face particular difficulties for complying with the proposed OELs. Therefore, the ACSH believes that in these sectors or processes, and possibly in other sectors, there may be need for using RPE to ensure that the workers are appropriately protected.

The ACSH strongly recommended the Commission to adopt as soon as possible OELs for this group of substances under Directive 2004/37/EC. It also agreed that it would be appropriate to introduce an OEL under the Directive 98/24/EC[96] for Nickel.

Benzene

The ACSH adopted its opinion for benzene on 4 June 2019[97], putting forward the following values and transition measures:

- Two years after entry into force of the Directive, a limit value of 0.5 ppm (1.65 mg/m³) will apply. Four years after entry into force of the Directive, a limit value of 0.2 ppm (0.66 mg/m³) will apply.

In addition to these values and transition measures, the ACSH agreed that the steel foundries sector faces particular difficulties for complying with the proposed OELs. Consequently, the ACSH believes that in this sector, and possibly in other sectors, there may be a need for using RPE to ensure that the workers are appropriately protected.

The ACSH strongly recommended the Commission to adopt as soon as possible a revised binding OEL for this substance under Directive 2004/37/EC.

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[94] https://circabc.europa.eu/ui/group/c9ba7ef7-03a1-41be-b69d-4ab203c3d93f/library/96b1c237-9dcc-4e3a-b29c-5f5eaf2974da/details

[95] See footnote 12

[96] Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01998L0024-20140325

[97] Available at: https://circabc.europa.eu/ui/group/c9ba7ef7-03a1-41be-b69d-4ab203c3d93f/library/f3a12f14-c7bd-42ce-899d-0e67d752c78a/details

The ACSH also agreed on the usefulness of biomonitoring (BLV) as proposed by RAC[98] but note that, at present, BLVs are not proposed under the CMD. The ACSH therefore suggested this BLV to be taken into consideration when developing the guidance on the practical use of biomonitoring.

3. Consultation of other stakeholders

In the context of the COWI study, consultation activites have been carried out to collect detailed information on the potential impacts of modifications to the CMD that is not available in published literature and internet searches. Although some information on OELs is available, limited information is available on concrete measures already in place and that would need to be implemented, should the OELs be modified. The information sought via consultation therefore included sizes of companies, sectors and processes that would be affected, number of workers exposed, current air concentrations of substances concerned (both 8-hour time weighted averages (8-h TWA) and 15-minutes reference periods), risk management measures currently in place, as well as risk management measures that would need to be implemented should the OELs be modified and associated costs.

Consultation carried out for the purposes of this study consisted of the following main activities:

- Questionnaires;
- Email requests (possibly in combination with questionnaires);
- Telephone interviews;
- Site visits;
- Face to face meetings;
- Workshops;

Mixed methods (combining e.g. questionnaire responses with telephone interviews and site visits) were adopted to ensure that a large number of organisations and individuals were able to provide data and provide their views within the time constraints and resource limits. Using mixed methods also enabled the study team to gather varying details of information and to explore information further where the need arose.

3.1. Targeted Online Questionnaires

Stakeholders were initially contacted via email. The e-mail provided an overview of the study and a link to the questionnaires. If stakeholders preferred to answer the questionnaire in a Word document (so that it could be shared among several colleagues, for example), the stakeholder was informed of the possibility to obtain a word-version upon request.

Three separate questionnaires were drawn up, each one created to gather information from different stakeholder groups:

- Questionnaire 1 was aimed at companies whose workers were exposed to nickel compounds, acrylonitrile or benzene;

[98] 0.7 µg benzene/L urine and 2 µg S-phenylmercapturic acid (SPMA)/g creatinine

- Questionnaire 2 was aimed at occupational health and safety experts; and
- Questionnaire 3 was aimed at Member State authorities.

The questions aimed to collect information on processes during which worker exposure to the substances in question is likely to occur, risk management measures that are already in place, current exposure concentrations, risk management measures that would need to be implemented should the limit be lowered, and any other impacts that could result from the introduction of EU level limits.

Although many of the responses provided a significant amount of useful information, many of them were not sufficiently detailed. Other methods of consultation, allowing experts to question and probe answers further (namely telephone interviews and site visits), were therefore required to obtain a more in-depth understanding of the potential impacts. This includes the above follow-ups.

3.2. Telephone interviews

Both national experts and substance experts were activated for the purposes of the telephone interviews. Telephone interviews were asked for in the online questionnaires as well as through direct email and phone contact.

The purpose of the telephone interviews was to gain more insight into the answers provided in response to the questionnaires. It enabled the collection of more detailed information on processes, to pinpoint exactly where exposure is likely to occur, investigating what types of risk management measures are already in place and how effective they are, as well as what risk management measures would be required if limits were lowered and other potential ramifications for the company.

3.3. Email requests

As supplement to the interviews various information was collected by email requests. The purpose and questions were similar to those explained above for telephone interviews.

3.4. Site visits

Companies whose activities are likely to be affected by the potential modifications to the CMD were also asked whether they would be willing to welcome members of the study team for a site visit. Companies to be visited, were identified via the questionnaire or the contact was established via EU trade associations.

The purpose of the site visits was to a gain a more operational understanding of the risk management measures currently in place to protect against exposure to the substances concerned, as well as of the risk management measures that would be needed should the CMD be modified.

Detailed notes from each site visit were drafted and sent back to the company to ensure that the information recorded was accurate. This process also enabled the company to add more detail and information to the study, where possible, and to confirm the level of confidentiality required to the information.

3.5. Face-to-face meetings

Face-to-face meetings were held with key EU associations for each of the substances. This aimed among other things to:

- facilitate the collection of more comprehensive data on the relevant sectors, and
- facilitate exchange of information collected as part of the associations' own socioeconomic assessments.

3.6. Workshops

In order to collect information from stakeholders and receive feedback, the consultant attended workshops with industry and workshops of the Working Party of Chemicals as listed in the table below.

Table 18: Workshops attended

Date	Substance	Subject, stakeholders and venue
22 Jan 2019	Benzene	Workshop on RMMs. Representatives of petroleum industry, petrochemical industry and Triskelion. Concawe offices in Brussels
22-23 Jan 2019	Benzene, nickel, acrylonitrile	Presentation of interim report. Working Party of Chemicals (WPC). European Commission, Luxembourg
19-20 Mar 2019	Benzene, nickel, acrylonitrile	Presentation of progress note. Working Party of Chemicals (WPC). European Commission, Luxembourg
29-30 Apr 2019	Benzene, nickel, acrylonitrile	Presentation of draft final report. Working Party of Chemicals (WPC). European Commission, Luxembourg

Source: COWI (2019)

3.7. Stakeholders targeted

The following table summarises information on stakeholder groups targeted and the interests represented. The table demonstrates that all relevant stakeholder groups have been reached out to.

Table 19: Stakeholders targeted and interests represented

Stakeholder type	Interests represented
EU Associations	Interest of industry
MS Authorities	Interest of MS authorities
Manufacturers/users	Interest of industry
National industry associations	Interest of industry
Trade Unions	Interest of workers
Occupational Health & Safety Professionals	No particular interest - contacted in order to obtain scientific

Stakeholder type	Interests represented
	information
ACSH Working Party on Chemicals (WPC)	Interests of industry, workers and MS authorities
Laboratories	No particular interest - contacted in order to obtain information on sampling and analysis

Source: COWI (2019)

Annex 3: Who is affected and how?

1. Practical implications of the initiative

Acrylonitrile

Table 20: Practical implications of the initiative for acrylonitrile

Citizens/Consumers	*Businesses*	*Administrations*
- Some of the quantified costs to business may be passed on to the citizens/consumers as increased prices. However, only limited impacts are expected. - Workers have the duty to comply with the dispositions provided by the employers as regards the use of preventive and protective measures necessary to comply with OSH legislation (e.g. the newly established OEL).	Employers must comply with the whole set of OSH national legislation provisions. Given the nature of the proposed amendment, this would mainly be: - implementation of the necessary risk management measures (RMMs) (e.g. closed systems, local exhaust ventilation, improved valves and flanges, limitation of number of workers exposed, personal protection equipment) in order to comply with the new OEL; - implementation of a sampling strategy and airborne concentrations measurement programme for the chemical agents with a new OEL, as part of the risk assessment process and effectiveness check of the existing measures; - ensure that acrylonitrile be managed in line with the provisions of the carcinogens and mutagens national legislation; - ensure compliance with other provisions in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the new OEL, collection of records, information to competent authorities, etc.).	Member States must transpose the amended Directive into national legislation: - assessment of the national scenario and potential impacts; - tripartite consultation of the proposal (workers, employers, authorities); - facilitate implementation of the national legislation by providing, among other measures, technical guidance to employers. These costs are minor in comparison to the overall costs of functioning incurred by the enforcement.

Benzene

Table 21: Practical implications of the initiative for benzene

Citizens/Consumers	*Businesses*	*Administrations*
- Some of the quantified costs to business may be passed on to the citizens/consumers as increased prices of e.g. petroleum products and some plastics. - Workers have the duty to comply with the dispositions provided by the employers as regards the use of preventive and protective measures necessary to comply with OSH legislation (e.g. the newly established OELs).	Employers must comply with the whole set of OSH national legislation provisions. Given the nature of the proposed amendment, this would mainly be: - implementation of the necessary risk management measures (RMMs) (e.g. substitution, closed systems, local exhaust ventilation, improved valves and flanges, limitation of number of workers exposed, personal protection equipment) in order to comply with the revised OEL; - implementation of a sampling strategy and airborne concentrations measurement programme for the chemical agents with a revised OELV, as part of the risk assessment process and effectiveness check of the existing measures; - ensure that benzene be managed in line with the provisions of the carcinogens and mutagens national legislation; - ensure compliance with other provisions in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the revised OEL, health surveillance, if appropriate, for chemical agents now under the scope of the legislation, collection of records, information to competent authorities, etc.).	Member States must transpose the amended Directive into national legislation: - assessment of the national scenario and potential impacts; - tripartite consultation of the proposal (workers, employers, authorities); - facilitate implementation of the national legislation by providing, among other measures, technical guidance to employers. These costs are minor in comparison to the overall costs of functioning incurred by the enforcement.

Nickel compounds

Table 22: Practical implications of the initiative for nickel compounds

Citizens/Consumers	*Businesses*	*Administrations*
- Some of the quantified costs to business may be passed on to the citizens/consumers as increased prices. However, the impact should be very limited. - Workers have the duty to comply with the dispositions provided by the employers as regards the use of preventive and protective measures necessary to comply with OSH legislation (e.g. the newly established OELs).	Employers must comply with the whole set of OSH national legislation provisions. Given the nature of the proposed amendment, this would mainly be: - implementation of the necessary risk management measures (RMMs) (e.g. closed systems, local exhaust ventilation, improved valves and flanges, limitation of number of workers exposed, personal protection equipment) in order to comply with the new OEL; - implementation of a sampling strategy and airborne concentrations measurement programme for the chemical agents with a new OEL, as part of the risk assessment process and effectiveness check of the existing measures; - ensure that nickel compounds are managed in line with the provisions of the carcinogens and mutagens national legislation; - ensure compliance with other provisions in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the new OEL, collection of records, information to competent authorities, etc.).	Member States must transpose the amended Directive into national legislation: - assessment of the national scenario and potential impacts; - tripartite consultation of the proposal (workers, employers, authorities); - facilitate implementation of the national legislation by providing, among other measures, technical guidance to employers. These costs are minor in comparison to the overall costs of functioning incurred by the enforcement

2. SUMMARY OF COSTS AND BENEFITS

Acrylonitrile

The table 23 below summarises the benefits as calculated on the basis of Method 1, which relies on Willingness to Pay (WTP) values for avoiding a case of mortality and morbidity. A low-high range has been provided that represents the lowest and highest values estimated in this study based on the different Method 1 approaches and assumptions. Estimates on the basis of Method 2, which relies on monetised Disability Adjusted Life Years (DALYs), are of a similar order of magnitude at OEL levels of 1 mg/m^3 inhalable.

Table 23: Overview of benefits for acrylonitrile

I. Overview of Benefits (total for all provisions), € over 60 years – Preferred Option (without transition measures)		
Description	***Amount***	***Comments***
Avoided costs for companies	€340,000 - €1,100,000	Reduced absenteeism, productivity losses and insurance payments. In addition, not quantified benefits include legal clarity, simplification in ensuring legal compliance and a more balanced level playing field for businesses across the EU.
Avoided costs for public sector	€27,000 - €89,000	Having reduced health care costs. Avoidance of loss of productivity and mitigation of financial loss of national social security systems, reducing the costs of healthcare and the loss of tax revenue due to morbidity and mortality. In addition, not quantified benefits include clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. Furthermore, the existence of an EU OEL eliminates the need for national public authorities to independently evaluate each carcinogen, removing an inefficiency of repetition of identical tasks.
Avoided costs for workers & families	METHOD 1: €440,000 - €5,800,000 METHOD 2: €583,000 - €5,430,000	The main intangible benefits are to workers and families: More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding premature deaths, less costs of informal care

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Table 24: Overview of costs for acrylonitrile

II. Overview of costs, € over 60 years – Preferred option (without transition measures)		
Description	***Stakeholders affected***	***Amount***
Compliance costs (one-off)	Companies	€30,000,000
Compliance costs (recurrent)	Companies	-€2,000,000
Monitoring costs	Companies	€0
Administrative costs	Public sector	€1,350,000
Single-market	Consumers	Limited impacts expected
Social costs (employment)	Workers & families	€0

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Nickel compounds

The table below summarises the benefits as calculated on the basis of Method 2, which relies on monetised Disability Adjusted Life Years (DALYs). Estimates on the basis of Method 1, which relies on Willingness to Pay (WTP) values for avoiding a case of mortality and morbidity, are approximately 70-80% of those under Method 1.

Table 25: Overview of benefits for nickel compounds

I. Overview of Benefits (total for all provisions), € over 60 years – Preferred Option (without transition measures)		
Description	***Amount***	***Comments***
Avoided costs for companies	€3,900,000	Reduced absenteeism, productivity losses and insurance payments. In addition, not quantified benefits include legal clarity, simplification in ensuring legal compliance and a more balanced level playing field for businesses across the EU.
Avoided costs for public sector	€2,200,000	Having reduced health care costs. Avoidance of loss of productivity and mitigation of financial loss of national social security systems, reducing the costs of healthcare and the loss of tax revenue due to morbidity and mortality. In addition, not quantified benefits include clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. Furthermore, the existence of an EU OELV eliminates the need for national public authorities to independently evaluate each carcinogen, removing an inefficiency of repetition of identical tasks.
Avoided costs for workers & families	€72,000,000 - €92,000,000	More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding premature deaths, less costs of informal care.

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Table 26: Overview of costs for nickel compounds

II. Overview of costs, € over 60 years – Preferred option (without transition measures)		
Description	***Stakeholders affected***	***Amount***
Compliance costs (one-off)	Companies	€4,300,000,000
Compliance costs (recurrent)	Companies	-€165,000,000
Monitoring costs	Companies	€2,500,000,000

Administrative costs	Public sector	€730,000
Single-market	Consumers	Limited impacts expected
Social costs (employment)	Workers & families	€779,000

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Benzene

The table below summarise the benefits as calculated on the bases of Method 1, which relies on Willingness to Pay (WTP) values for morbidity. Estimates on the basis of Method 2, which relies on monetised Disability Adjusted Life Years (DALYs), were about 60% of the values calculated with Method 1.

Table 27: Overview of benefits for benzene

I. Overview of Benefits (total for all provisions), € over 60 years – Preferred Option (without transition measures)		
Description	***Amount***	***Comments***
Avoided costs for companies	€2,000,000	Reduced absenteeism, productivity losses and insurance payments. In addition, not quantified benefits include legal clarity, simplification in ensuring legal compliance and a more balanced level playing field for businesses across the EU.
Avoided costs for public sector	€2,500,000	Having reduced health care costs. Avoidance of loss of productivity and mitigation of financial loss of national social security systems, reducing the costs of healthcare and the loss of tax revenue due to morbidity and mortality. In addition, not quantified benefits include clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. Furthermore, the existence of an EU OELV eliminates the need for national public authorities to independently evaluate each carcinogen, removing an inefficiency of repetition of identical tasks.
Avoided costs for workers & families	€121,000,000 - €198,000,000	More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding premature deaths, less costs of informal care.

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Table 28: Overview of costs for benzene

II. Overview of costs, € over 60 years – Preferred option (without transition measures)		
Description	***Stakeholders affected***	***Amount***

Compliance costs (one-off)	Companies	€2,461,000,000
Compliance costs (recurrent)	Companies	€5,149,000,000
Monitoring costs	Companies	€0
Administrative costs	Public sector	€300,000
Single-market	Consumers	Limited impacts expected – small price increase for fuels
Social costs (employment)	Workers & families	€0

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Annex 4: Analytical methods

1. MONETISATION OF THE HEALTH IMPACTS

1.1. Health impacts

The introduction of an OEL is expected to result in a reduction in the occupational exposure to the carcinogen concerned. The extent of such reduction depends on the current levels of exposure, as well as on the projected future levels of exposure in the absence of the proposed measure, i.e. the 'baseline scenario'.

For a given reduction in exposure levels, it is then necessary to estimate the expected decrease in the incidence of cancer cases and other non cancer health effects over a given timeframe to the substance in question.

The current and future cases of ill health have been estimated for both cancer and non-cancer endpoints using the following inputs:

- The Exposure Risk Relationships (ERRs) and Dose Response Relationships (DRRs);
- The numbers of workers exposed;
- The exposure concentrations; and
- Trends in the exposed workforce and exposure concentrations.

On this basis, we can therefore calculate the health impact which can be defined as the number of persons (“cases”), either suffering from cancer and/or experiencing some noncancer health effects due to this occupational exposure.

It has to be kept in mind that

- the ERR only applies on the most critical cancer site, which is given by the assessment of the European Chemicals Agency / Committee for Risk Assessment (ECHA/RAC), and only comment qualitatively on further cancer sites, which may be linked to exposure to the respective substance;

- the DRRs are derived by referring to the most critical non-cancer effects quantitavely. The effects, which were regarded as the most critical ones by RAC are selected and we only comment qualitatively on further non-cancer effects, which may be linked to exposure to the respective substance

- as there is even less scientific consensus on the increase of effect severity with increasing exposure concentration and the respective data are often not adapted to the workplace exposure scenario, we focus on the *fraction of workers affected* at the different exposure levels, when we establish a DRR, without taking into account the increase of severity of effects.

Therefore, the calculated health impact (e.g., in terms of “number of estimated cases with health impairments”) is not identical to the “real” health impact, but is just an approximation, which may underestimate the full impact of the occupational exposure to the respective substances. However, there are other uncertainties leading to under- or overstimates. These are further developed further in this annex.

Exposure Risk Relationships

The starting point for a cancer risk impact assessment is the OEL proposed by RAC and the respective RAC opinion, together with the annexed background report. For the three substances, RAC found significant arguments for a mode-of-action based threshold and used this concept for proposing OELs. No conclusions regarding incidence and severity of effects above the OEL is presented in these reports.

The OEL proposed by RAC is used to define a zero response, i.e., 0 % of the exposed individuals are assumed to suffer from the respective health effect, if exposed for all of their working life time to this OEL. RAC does not derive any ERR for the range above the proposed OEL. As the ERR is essential for the benefit assessment of the current study, an ERR has been established for this impact assessment.

As part of this, it has been assessed which of the existing dose-response relationships is the most adequate, following the mechanistic conclusions in the RAC opinion. Based on RAC’s assessment we use, where available, sublinear exposure risk relationships of high quality, which follow a similar mode-of-action argumentation as RAC. They are used to describe cancer risks above the OEL.

If the ERR is not already provided for a working lifetime exposure scenario, the respective transformation has to be calculated: working life time is assumed to be 40 years, with work day exposure for 8 hours/day, 5 day/week in 48 weeks of a year. It is a conservative estimate based on the most critical cancer site (cancer risk associated with highest risk).

Dose Response relationships

For non-cancer endpoints, the RAC opinion as well as other recent evaluations and literature reports are scrutinized to identify the most relevant endpoints for humans. Relevance means that existing information makes it likely that effects might occur in humans at exposure levels above the OEL proposed by RAC, which are of relevance in European industries. Human data are preferred over experimental animal data. Experimental data are used as supportive information only, where sufficient human dose-response information is available to derive a DRR. Where insufficient human information is available, we have to rely on experimental animal data.

Data from original toxicological and epidemiological studies, referenced by RAC or national committees as being qualified and demonstrating a dose-response, are selected and searched for effect levels linked to a specific fraction of the exposed (humans or animals). If not contradicted by the overall weight of evidence, this slope reported in such a study is adopted for the DRR. If effects are reported on a continuous scale, this needs to be transformed to quantal data (i.e. the incidence of effects in the exposed population), which often requires certain assumptions.

In case animal data are used, data are transformed to the human situation, e.g. by applying allometric scaling factors in accordance with the ECHA Guidance on Information Requirements and Chemical Safety Assessment, R.8; Characterisation of dose [concentration]-response for human health[99].

The number of workers exposed

It is important to calculate the number of workers potentially exposed to a substance in order to calculate the potential benefits of implementing any new measures. For each substance discussed in this Impact Assessment Report, several datasets have been identified.

As soon as these datasets have been identified, there is a need to select those which are the most representative of the current reality. For example, only datasets on acrylonitrile at the EU level have been selected. Indeed, it is likely that there are significant differences between the Member States in terms of numbers of workers exposed. Therefore, extrapolating the number of workers exposed at the EU level on the basis of figures at Member States level would lead to wrong estimates.

1.2. Monetisation of the health impacts

Specific guidance is provided in the Better Regulation (BR) Toolbox for health impacts (BR Tool #31). This is summarised in the table below.

Table 29: Better Regulation Toolbox on social impacts

Aspect	Guidance
Health impacts	Direct impacts Indirect impacts: does the option influence the socio-economic environment that can determine health status? To assess direct and indirect health impacts monetary and non-monetary methodologies can be used. Non-monetary approaches: Quality adjusted life years (QALYs), Disability adjusted life years) (DALYs), Healthy life years (HLYs). Monetary approaches: preference-based approaches Willingness to pay (WTP), Willingness to accept (WTA) -> Value of Statistical Life (VOSL), Value of Life-Year (VOLY), accounting-style approaches (cost of illness method=only medical expenses, human capital method=loss of future earnings in case of disability or premature death)

Source: COWI (2019)

Focusing on the example of cancer, the costs of cancer can be divided into:

[99] https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/e153243a-03f0-44c5-8808-88af66223258

- **Direct costs:** These are the costs of healthcare, in other words, the medical costs associated with the treatment of cancer and other costs, including non-medical costs, that arise directly as a result of cancer, for example those related with care and the costs to employers. Healthcare costs are those associated with the treatment and services patients receive, including the cost of hospitalisation, surgery, physician visits, radiation therapy and chemotherapy/ immunotherapy. Depending on the structure of national health care provision, these costs may be borne fully or partially by the government (tax payers). Direct medical costs associated with cancer vary significantly by cancer type and also vary over time. Indeed, it has been noted that cancer costs are highest in the initial period following diagnosis and, among patients who die from their disease, at the end of life; they are lowest in the period between the initial and end of life periods, following a "u-shaped" curve (Yabroff et al., 2012)[100]. Other direct costs may be incurred by the patients (say the cost of transport to attend appointments) but also by their family/friends, for example, through providing unpaid care.

- **Indirect costs:** These are the monetary losses associated with the time spent receiving medical care, including productivity losses due to time spent away from work or other usual activities and lost productivity due to premature death. Employers might also bear costs indirectly through *inter alia* loss of output; payments related to sick leave; administrative costs related to a worker's absence; additional recruitment costs; loss of experience/expertise; overtime working; compensation payments (although this may be covered by some form of employer's liability insurance); and insurance premiums. Depending on the national structure of social security provision, the government (tax payers) may also bear the costs of any disability/social security payments and will also suffer losses through foregone tax receipts.

- **Intangible costs:** These include the non-financial 'human' losses associated with cancer, e.g. reduced quality of life, pain, suffering, anxiety and grief.

In economic impact terms, the total social costs[101] of ill health are measured by the costs borne for health care provision, together with lost output (including productivity losses), gross wage and non-wage labour costs of absent workers (such as loss of experience), administrative costs and the intangible costs. These represent the direct and indirect resource costs and the non-market 'external' costs of illness. The other costs listed above (e.g. insurance premiums) relate to what are commonly referred to as 'transfer payments', which do not give rise to net welfare effects. As a result, they are not considered in economic analyses, even though they may be important in financial terms to an individual worker or an employer.

[100] Yabroff KR et al. (2012): Economic burden of cancer in the US: Estimates, projections and future research, Cancer Epidemiology Biomarkers & Prevention, 20 (20) pp 2006-2014, available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3191884/
[101] From a welfare economic perspective.

1.3. The Model

1.3.1. Introduction

The following table provides a first overview on the expected key endpoints per substance.

Table 30: Carcinogenic and non-carcinogenic endpoints

Substance	Carcinogenic endpoints	Non-carcinogenic endpoints
Nickel and compounds	Lung cancer	Pulmonary fibrosis, reproductive toxicity
Acrylonitrile	Brain cancer	Neurotoxicity, nasal irritation
Benzene	Leukaemia	Leukocytopenia

Source: COWI (2019)

The key model inputs are summarised below. The inputs are those parameters whose variation changes the results and for which the model is run multiple times to derive a benefits curve.

Table 31: Key model inputs

Parameter	**Explanation**
Rx: Estimate of the risk or fraction of workers affected	Exposure-Risk Relationship (ERR) or Dose-Response Relationship (DRR)
ExW: Exposed workforce	Number of workers exposed at different points in time
Cx: Exposure concentration	8-hr TWA (time-weighted average) that the workers are exposed to (real concentration, i.e. if personal protection equipment (PPE) is currently worn, the measured concentrations are adjusted to take into account PPE where possible)

Source: COWI (2019)

In addition to the inputs, the model is underpinned by a range of default assumptions regarding the onset of the disease and its effects. These assumptions differ by substance but do not change depending on the variations in the input data. Some of these assumptions are a simplification of complex real life scenarios or best estimates (where authoritative evidence could not be identified from readily available literature).

The key areas in which assumptions had to be made to enable the calculations are set out below.

Table 32: Key assumptions and their consequences for the sensitivity analysis

Parameter	**Explanation**

Onset of the disease	
MinEx	The minimum exposure duration required to develop the endpoint
MaxEx	The time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk of effects do not increase)
ModEx	The modelled exposure duration (the ERRs and DRRs are for a 40 year period)
Lat	The latency with which the effect is demonstrated
Dist	The distribution of cases over the period between MinEx and 60 years
The effects of the disease	
Mortality	Mortality rate as a result of the relevant condition
Value of a case	Monetary value of a case taking into account the direct, indirect, and intangible costs

Source: COWI (2019)

The model provides a good approximation of the order of magnitude of the expected impacts and the core calculations are supported by sensitivity analysis. The outputs of the model include:

- The number of new cases for each health endpoint assigned to a specific year in the 60 year assessment period;
- The Present Value (PV) of the direct, indirect, and intangible costs of each case.

1.3.2. Key model inputs

i. Rx: estimate of the risk or fraction of workers affected

The estimate of the risk or fraction of workers affected:

- For cancer: Exposure-Risk Relationship (ERR) i.e. excess risk of developing cancer due to lifetime occupational exposure to a substance (taken here to mean 40 years); and
- For non-cancer endpoints: Dose-Response-Relationship (DRR), i.e. the proportion of workers that will develop an endpoint when exposed to a certain level.

ii. ExW: Exposed workers

Several scenarios are modelled for the exposed workforce. It is not possible to take into account all the complexities of real life workforce changes and these scenarios are theoretical constructs/simplifications which are designed to provide order of magnitude estimates without the need to construct a very large number of scenarios to cover all the types of workforce dynamics.

Two distinct issues are usually covered under the term ‘turnover’. Primarily, turnover refers to the natural turnover rate resulting from workers leaving their employer and new workers joining. In addition, it can refer to the turnover triggered by those that are absent from work due to illness and replaced by others.

However, turnover refers to the rate by which workers change employment type as it is considered that often workers when leaving one employer are employed for similar work by another employer. As consequence workers may be exposed for longer time in similar jobs that indicated by the average times workers are employed by the individual employer.

It is assumed that there is a turnover of 5% per year. The 5% per year is lower than the turnover ratios in most of the published literature and Eurostat, which are typically derived at the level of individual companies rather than sectors.

iii. Cx: Exposure concentration

The method has been applied for all substances under CMD 4 as follows:

- Exposures are for each sector or sub-sector represented by log-normal distributions fitted to available data on e.g. median values and 95th percentiles.
- The exposure distributions are considered to represent the variation in the exposure of each worker and among workers;
- For all concentrations below the threshold (if any), the effect is 0;
- By introduction of the OELV, it is assumed that the 95th percentile should be reduced to a level at or below the OELV;
- As a result of the implemented measures, the general exposure levels would be reduced at a rate comparable to the reduction in the 95th percentile i.e. the entire distribution is changed. The new percentiles can be calculated as: $\text{percentile}_{new} = \text{percentile}_{old} * \text{OEL} / 95^{th}{}_{old}$. By this, it is assumed that the variance of the lognormal distribution is the same before and after introduction of the OEL, but the AM is reduced with the same ratio as the 95th percentile.
- Some 5% of the exposure levels of the new percentile will be above the OEL. In some of the previous CMD projects it has been assumed that all exposure above the OEL is reduced to the OEL, but it follows from the 95th percentile model that some measured concentrations would still be above the OEL.

In order to reduce the possible overestimation of the effect of introduction of an OEL, to the extent the available data allow, specific distributions should be developed for subsectors, SEGs, specific work areas (less well defined than the SEGs), regional sectors (e.g. different distribution for MS with an OEL and MS without an OEL), etc. The challenge, however, have not been to obtain exposure concentration datasets for different SEGs, but to obtain detailed data on number of workers within the different SEGs. In practice, it has been the availability of data on workers by SEG or subsectors which has been determining for the necessary aggregation into sectors.

When establishing the various exposure distributions, the existing OELs in MS have been taken into account. Consequently, it has not been necessary to take the existing OELs into account when estimating the effects of introduction of an OEL. For nickel compounds, however, due to complexity and the fact that the national OELs address different fractions, it has not be possible to fully reflect existing OELs in the exposure distributions.

1.3.3. Key assumptions

i. MinEx and MaxEx – The minimum exposure duration required to develop the endpoint

The model assumes that no cases arise until the minimum exposure duration required to develop the endpoint (MinEx) has expired, see table 33 below. The default MinEx is two years for cancer, a standard assumption for a chronic condition. The minimum exposure periods in the table below have been derived using a precautionary approach that maximises worker protection. The MaxEx reflect the time needed to reach the maximum risk (i.e. after the MaxEx has been reached, the risk of effects do not increase).

Table 33: Minimum & maximum exposure duration to develop a condition (MinEx & MaxEx)

Substance	Endpoint	MinEx (years)	MaxEx (years)
Nickel compounds	Lung cancer	2	40
Nickel compounds	Pulmonary fibrosis	1	22
Nickel compounds	Reprotoxic toxicity	0	0.25
Acrylonitrile	Brain cancer	2	40
Acrylonitrile	Irritation	0	2
Benzene	Leukaemia	2	20
Benzene	Leukocytopenia (haematotoxic effects)	0	6

Source: COWI (2019)

ii. Dist – the distribution of cases between start of exposure and Year 59

Valuing the cost of occupational illness involves applying discounted costs to future cases which requires that the estimated cases over a 60 year period are assigned to specific years. However, the ERRs and DRRs developed under this study are for 40 years of exposure.

'Dist' refers to the distribution of cases between start of exposure and Year 59, also taking MinEx into account. This differs between endpoints. The main difference is between cancer and non-cancer endpoints;

iii. Cancer

For reasons of simplicity, the following approach is used to distribute the total 40-year cancer **risk** (i.e. not incidence but risk since incidence is delayed due to latency) over the 60 year period: It is assumed that no risk arises until MinEx has expired. It is assumed that, subsequently, the distribution is linear, i.e. 0% of the excess risk arises in year 2 and 100% of the excess risk arises by year 40. The annual number of cases after MinEX is then used as a proxy for the number of cases until 60 years.

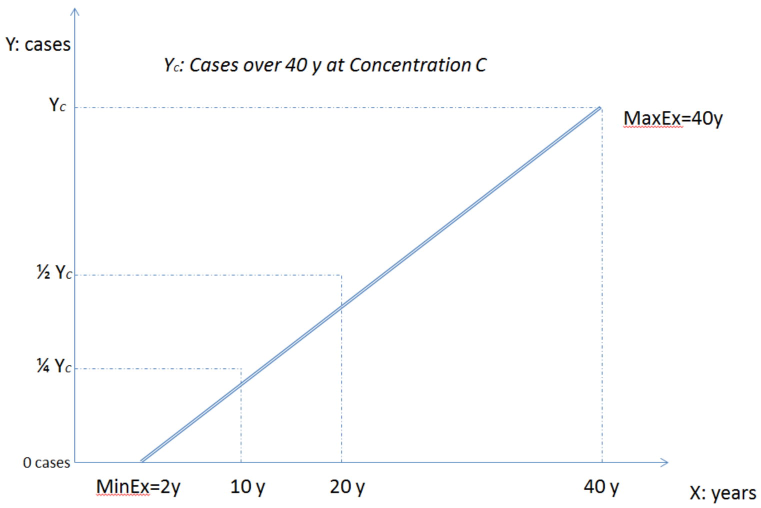

Figure 4 - Brain cancer risk of exposure to acrylonitrile – distribution over time (source: COWI study (2019))

iv. Default for non-cancer endpoints

While the further calculation is straightforward for the cancer endpoints, the estimations are more challenging for the non-cancer endpoints.

Typically, the fraction affected achieves that predicted by the DRR as soon as MaxEx expires and remains constant over the 40 year DRR period (although the certainty of the 'fraction' estimated on the basis of the DRR increases towards the end of the period). As a default assumption, two years has been chosen as a conservative MaxEx.

With a MinEx of 0 year and a MaxEx of 2 years for cancer endpoints, the fraction affected that is calculated on the basis of the DRR is the same between 2 years and 40 years and increases in a linear manner between Year 0 and Year 2.

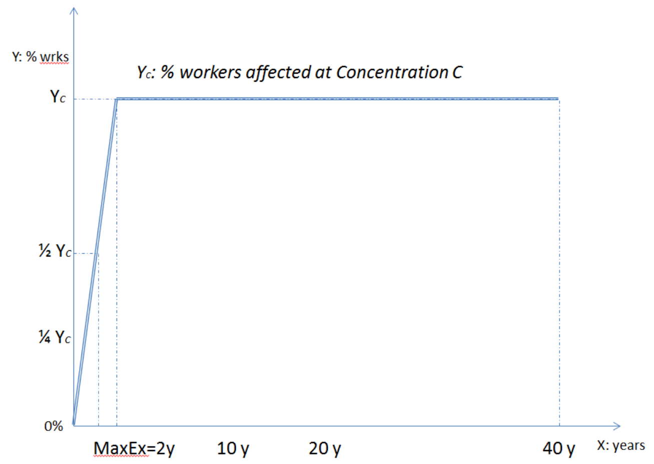

Figure 5 - Non-cancer endpoints – fraction affected over time - example with a MaxEx of 2 years (source: COWI (2019))

v. Latency

Cancer endpoints

Similar to the approach used in CMD 3, by way of simplification, a single latency value is used for the calculation of the core scenario. According to Rushton et al. (2012), all solid tumours are expected to have a latency of 10-50 years, meaning that the average latency is 30 years. A latency of 30 years is used as a default for cancer endpoints.

As noted in the methodological note for CMD 3, 40 years of exposure and 30 years of latency would translate into a 70-year assessment period which is longer than the assessment period used in the CMD 3 study and the current study. In order for the assessment not to underestimate the benefits (longer latency reduces the benefits since they are discounted at lower factors) the CMD 3 study and the previous Impact Assessments for the OELs under the CMD which relied on an assessment period of 60 years, used a latency period of 10 years.

In order to avoid underestimations of the current burden of disease and avoid inconsistences in the applied latency periods used for estimations of the current and future burden of disease, latency periods in accordance with those reported in the literature have been applied. Latency periods for the cancer endpoints are shown in the table below.

Table 34: Latency (Lat) periods of cancer endpoints

Substance	Endpoint	Lat (years)
Nickel compounds	Lung cancer	30
Acrylonitrile	Brain cancer	30
Benzene	Leukaemia	5

Source: COWI (2019)

Non-cancer endpoints

The estimated latency period for the non-cancer endpoints in this study is 0 years. There is very limited evidence for latency of the relevant non-cancer conditions.

Table 35: Latency (Lat) periods of non-cancer endpoints

Substance	Endpoint	Lat (years)
Nickel compounds	Pulmonary fibrosis	0
Nickel compounds	Reprotoxic toxicity	0
Acrylonitrile	Irritation	0
Benzene	Leukocytopenia (haematotoxic effects)	0

Source: COWI (2019)

vi. ModEX - the modelled exposure duration

The ERRs and DRRs are for a 40 year period. The modelled exposure duration is thus 40 years.

Whilst it is unlikely that a single worker is exposed to a substance at a constant concentration throughout their whole working life, the 40 year period has been chosen in order to be protective to workers by assuming a worst-case scenario. The evidence used for the development of the ERR means that the greatest certainty about the ERR is at lifetime exposure, i.e. 40 years.

It is highly likely that the real exposure duration is shorter than ModEx (the modelled exposure duration) and this have been taken into account by use of the staff turnover for the estimations as described elsewhere.

vii. MoR – mortality rate

Mortality rate as a result of the relevant condition is important since different monetary values are applied to mortality and morbidity. The mortality rates used in the model are given below.

Table 36: Mortality rate (MoR)

Substance	Endpoint	MoR

Nickel compounds	Lung cancer	80
Nickel compounds	Pulmonary fibrosis	0
Nickel compounds	Reprotoxic toxicity	0
Acrylonitrile	Brain cancer	80
Acrylonitrile	Irritation	0
Benzene	Leukaemia	80
Benzene	Leukocytopenia (haematotoxic effects)	0

Source: COWI (2019)

viii. Treatment period

The treatment periods used in the model are given below. The end of the treatment period signifies either a fatal or illness-free outcome.

Table 37: Treatment period

Substance	Endpoint	Treatment period (years)
Nickel compounds	Lung cancer	5
Nickel compounds	Pulmonary fibrosis	5
Nickel compounds	Reprotoxic toxicity	5
Acrylonitrile	Brain cancer	5
Acrylonitrile	Irritation	1
Benzene	Leukaemia	5
Benzene	Leukocytopenia (haematotoxic effects)	1

Source: COWI (2019)

ix. Monetary value of the relevant endpoint

The approach to the monetisation of ill health effects is based on the following approach.

Table 38: Benefits framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[102]	Opportunity cost of unpaid care (i.e. the monetary value of the working and/or leisure time that relatives or friends provide to those with cancer)
	Cost for employers (e.g. liability insurance)	Cost to employers due to insurance payments and absence from work
Indirect	Mortality – productivity loss	The economic loss to society due to premature death
	Morbidity – lost working days	Loss of earnings and output due to absence from work due to illness or treatment
Intangible	Approach 1 WTP: Mortality	A monetary value of the impact on quality of life of affected workers
	Approach 1 WTP: Morbidity	
	Approach 2 DALY: Mortality	
	Approach 2 DALY: Morbidity	

Source: COWI (2019)

Two approaches to the monetisation of intangibles have been adopted for the purposes of this study:

- Approach 1: Application of a single WTP value to each case; and
- Approach 2: Use of DALYs (Disability adjusted life year) and their monetisation.

1.4. Benefits assessment

The health benefits of implementing new or revised OELs are then calculated in terms of the costs of ill heatlh avoided.

Benefits to workers & families

The direct and indirect resource costs are estimated using market-based information, for example, data on health care costs, and estimates of lost output (i.e. the value of a day's work).

[102] A decision has been taken to include informal care costs in this analysis even though some elements of these costs may also have been included in individuals' willingness to pay values to avoid a future case of ill health. This decision may result in an overestimate of the benefits as generated by this study.

Added to these are the 'human' or intangible costs associated with a case, which are measured in terms of an individual's willingness to pay for the reduction in the risk of mortality or morbidity (Approach 1) or monetised DALYs (Approach 2).

Under Approach 1, the most commonly used means of estimating individuals' WTP for a reduction in the risk of an illness is through the use of experimental markets and survey techniques (e.g. contingent valuation or contingent ranking studies) to directly elicit individuals' WTP for a reduction in the risk of death or morbidity.

The key measures are the value of a statistical life – a VSL – and the value of a case of morbidity (value of cancer morbidity VCM or value of morbidity VM). The VSL is essentially a measure of a change in the risk of fatality, where this is found by determining individuals' willingness to pay for a small change in risk which is then summed across the population at risk.

1.4.1. Benefits to employers

The benefits of introducing OELVs have obvious benefits for workers, namely in terms of their health but also, indirectly, on their earnings. Employers will also reap benefits from their employees being less at risk of occupational illness. Such benefits include:

- higher labour productivity resulting from reductions in absenteeism and associated production losses;
- reduced administrative or legal costs relating to employees who are ill; and
- reduced sick leave payments.

1.4.2. Benefit to employers and workers – lost earnings and productivity losses

Individuals will incur costs associated with their inability to work in terms of a loss of earnings, including losses linked to days of for treatment as well as days off due to illness. Luengo-Fernandez et al. (2013) developed estimate of the magnitude of such costs by Member State in terms of an average cost per fatal or non-fatal cancer. These included what are referred to as "productivity losses" due to early death and then lost working days due to morbidity effects. Across all cancers, an average figure of €5,047 is given for productivity losses and €1,118 for the costs associated with lost working days due to morbidity effects (with these based on lost wages as the measure of lost output).

There are difficulties in including the type of estimates generated by Luengo-Fernandez et al. (2013) for lost working days within the analysis carried out here due to the potential for double counting. It is not clear whether the figures adopted in this study to reflect the intangible or human costs of cancer mortality and morbidity (i.e. €4 million and €400,000 respectively) also include an element related to the loss of income. If they do, then to include a separate cost item to reflect lost income would result in a double-counting of impacts.

The decision has therefore been taken not to include an additional element for lost income for mortality effects. However, due to uncertainty as to what may be captured by the value adopted here for cancer morbidity, lost income due to lost working days is considered within this analysis.

This inclusion may result in an overestimation of the economic costs associated with cancer morbidity. However, the exclusion of lost output for cancer mortalities may also lead to an underestimation if these are not fully accounted for within the value of a statistical life figure used here to reflect the intangible or human costs of a cancer.

1.4.3. Benefits to the public sector – cost of healthcare

Cancer cases: key data from Luengo-Fernandez, et al (2013)[103] have been used for the calculation of the avoided healthcare costs of illness. EUR 7000 is used in the model as the average cost for "all cancers".

Leukocytopenia: there is no available data on the clinical process for leukocytopenia. It is assumed that performing a diagnosis will require visits to the general practitioner followed by consultation with specialists. Probably not all patients would need consultations with specialist including hospital. Consultation at the general practitioner, and subsequent treatment, might cost a few hundred euro, while the costs of specialist consultation could be several thousand euro. On average the cost for getting the diagnosis and the subsequent treatment is estimated at €1,000.

Pulmonary morbidity: The cost of treatment for pulmonary morbidity is based upon costs for chronic obstructive pulmonary disease (COPD). COPD is largely caused by smoking and is characterised by progressive, partially reversible airflow obstruction, systemic manifestations (skeletal muscle dysfunction, depression, and secondary polycythaemia), and increasing frequency and severity of exacerbations. The main symptoms, which are usually insidious in onset and progressive, are shortness of breath and inability to tolerate physical activity[104]. As such, the UK Department of Health Reference costs 2015/16[105] provide a comprehensive estimate of the costs associated with the treatment of the different conditions. From these, the healthcare costs for pulmonary morbidity are estimated at €1,000 per year.

Reproductive toxicity (miscarriages): The cost of treatment for reproductive toxicity (miscarriages) is taken from UK's National Health Service (NHS) Reference costs[106] where the cost of a "Threatened or Spontaneous Miscarriage, with Interventions" is £1,908 and that of a "Threatened or Spontaneous Miscarriage, without Interventions" is £580. From these, the healthcare costs for reproductive toxicity (miscarriages) are estimated at €1,000 per year.

Nasal irritation: no data has been identified for the cost of treatment for nasal irritation, €200/year has been assumed since different severities are covered (from mild which require no treatment to severe).

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[103] Luengo-Fernandez et al. (2013): *Economic burden of cancer across the European Union: apopulation-based cost analysis;* Lancet Oncology; 14; 1165-75

[104] McIvor A. (2007): *Chronic Obstructive Pulmonary Disease*. BMJ 334; 798

[105] UK DoH (2016): *UK Department of Health, Reference costs 2016*. Available at: https://www.gov.uk/government/publications/nhs-reference-costs-2015-to-2016

[106] NHS (2017) : Reference costs. Available at: https://improvement.nhs.uk/resources/reference-costs/

2. COST MODEL

2.1. Compliance cost assessment

2.1.1. Introduction

This section describes the methodology for compliance cost assessment used across the three substances. For benzene, some costs estimates has been based on sector-specific studies.

The compliance costs for companies are basically estimated on the basis of:

- Risk Management Measures (RMMs) needed for reducing the air exposure levels from the actual levels to the target level.
- The costs of the RMMs (on-off and recurrent) for each company and/or workstation.
- The life span of the RMMs.
- Number of companies and/or workstations.

The costs are calculated in a worksheet model. For some sectors, where non-specific data are available, a likelihood model is applied. The likelihood model calculates the costs for a group of similar companies incurred in reducing air exposure to a target OEL based on an assumed sequence of RMM implementation which is determined by suitability, effectiveness, and cost. The model is run several times to construct a continuous cost curve.

For other sectors, where the RMMs to be applied are more well-described, a more simple model is applied, but the same unit costs and life span parameters are used as in the more complex model.

2.1.2. Key model inputs and assumptions

i. Discount rate

The static discount rate is 4%: this is taken over the 60 year period. A dynamic discount rate is taken in the sensitivity analysis. The dynamic rates start at 4% for the first 20 years; it then decreases to 3% for the remaining 40 years.

ii. Affected workers and worstations

Each company size was in the likelihood model assumed to have an average number of workers affected and associated workstations requiring adjustment, shown in the table below.

Table 39: Number of workers and workstations

Size of company	Number of workers affected	Number of workstations
Small	2	1
Medium	27	14
Large	75	40

Source: COWI (2019)

Three different costs, all present values for 60 years, are calculated: TOTAL, (one-off + recurrent) one-off costs, and recurrent.

iii. RMMs considered

The likelihood model considers following types of RMMs:

- Local Exhaust Ventilation (LEV), extraction at source;
- Worker enclosures (WE), i.e. physical separation of workers in an enclosure or control room;
- Respiratory Protective Equipment (RPE);
- General Dilution Ventilation (GDV);
- Organisational & hygiene measures (OH).

For reduction of fugitive emission (e.g. in coke plants or in the petroleum sector) other types of measures such as improved valves, pumps, etc. are considered.

iv. RMMs effectiveness

Every RMM has a different level of effectiveness in reducing the workers exposure to the substances. The percentage reduction in exposure due to each type of RMM used in the analysis is shown below.

Table 40: Percentage reduction in exposure achieved with RMM

Type of RMM	% reduction in exposure
Discontinuation	100%
Substitution possible	100%
Substitution not possible	0%
Rework	50%
Full enclosure	99.5%
Partial enclosure	90%
Open hood	80%
No LEV	0%
Pressurised or sealed	99.5%
Simple enclosed cab	80%
No enclosure	0%
Breathing apparatus	99.5%
HEPA (high efficiency particulate air) filter	95%

Simple mask	60%
No mask	0%
Organisational measures	30%
No organisational measures	0%
General dilution ventilation	30%
No general ventilation	0%

Source: COWI (2019)

v. RMMs costs

Table 41: Cost of various RMMs in €

Size of company	**Small 2 workers exposed Exposed workers on 1 machine**			**Medium 27 workers exposed 14 machines**			**Large 75 workers 40 machines**		
Type of RMM	One-off 2019	Lifespan years	Recurrent (% of one-off)	One-off 2019	Lifespan years	Recurrent (% of one-off)	One-off 2019	Lifespan years	Recurrent (% of one-off))
RWK: Rework	25,000			350,000			1,000,000		
LEV 3: Full enclosure	45,000	20	10%	440,000	20	10%	1,700,000	20	10%
LEV2: Partial enclosure	30,000	20	10%	240,000	20	10%	650,000	20	10%
LEV1: Open hood	7,000	20	10%	90,000	20	10%	260,000	20	10%
WE 2: Pressurised or sealed	30,000	20	10%	240,000	20	10%	650,000	20	10%
WE 1: Simple enclosed cab	7,000	20	10%	90,000	20	10%	260,000	20	10%
RPE 3: Breathing apparatus	2,600	2	1,000%	35,000	2	1,000%	100,000	2	1,000%
RPE 3a: Powered helmets or full	2,000	3	30%	27,000	3	30%	40,000	3	30%

face mask									
RPE2: HEPA filter	300	Mask: 1 month, Filter: 1 month	50%	4,000	Mask: 1 month, Filter: 1 month	50%	11,000	Mask: 1 month, Filter: 1 month	50%
RPE 1: Simple mask	500	Not relevant, 1 per day	Not relevant but one-off costs 2019 incurred every year	7,000	Not relevant, 1 per day	Not relevant but one-off costs 2019 incurred every year	20,000	Not relevant, 1 per day	Not relevant but one-off costs 2019 incurred every year
OH 1: Organisational measures	2,000		50%	27,000		50%	75,000		50%
GDV 1: General dilution ventilation	6,000	20	30%	40,000	20	30%	100,000	20	30%

Source: COWI (2019)

vi. Sectoral characteristics that determine suitability of RMMs

For sectors or subsectors, where specific information on RMMs to be applied is not known, the likelihood model determines the suitability of RMMs on the basis of sectoral characteristics.

The amount of exposure is split into work where the worker is exposed to the substance for less than an hour a day and for more than an hour a day. This also equates to exposure for more or less than 2.5 days/month. Many production activities only occasionally use the substances. Where the exposure is less than an hour a day, it is acceptable, and often more cost effective, to use personal protective equipment (PPE) such as masks with filters or breathing apparatus.

The form of substance to which workers are exposed varies considerably from dust and fibres to vapour, fumes, gas, mist and aerosol. Again, the form of substance has a direct bearing on the types of RMM that are suitable. For example, general dilution ventilation is not advised for removing dust as it tends to stir it up and spread it around. For this analysis, the substance form is split into two types: dust which also includes fibres; and gas which includes all the other types.

The extent of the spread is the final characteristic that affects the choice of RMM and this is split into three types: local, diffuse and peripheral. Local means the dust or gas is created around a specific machine and often means that highly targeted ventilation can effectively remove the chemical. Other processes spread the substance over a wider area and this is known as diffuse. In this case, dilution ventilation, workers enclosures or full enclosures are more suitable, the choice depending upon the decrease in exposure required. Peripheral means that the substance spreads more widely and cause exposure to workers beyond the area where the substance is being worked. This means that administrators, managers and sales staff may be exposed.

In the table below, the types of RMM that are suitable or not for each amount of exposure, form of substance and extent of spread are shown. These values were built into the cost model.

Table 42: Suitability of various RMMs to amount of exposure, form of the substance and extent of spread

Type of RMM	<1h	>1h	Dust	Gas	Local	Diffuse	Peripheral
Discontinuation & Substitution	Y	Y	Y	Y	Y	Y	Y
Rework	Y	Y	Y	Y	Y	Y	Y
Full enclosure	Y	Y	Y	Y	Y	Y	Y
Partial enclosure	Y	Y	Y	Y	Y	Y	Y
Open hood	Y	Y	Y	Y	Y	Y	Y
No LEV	Y	Y	Y	Y	Y	Y	Y
Pressurised or sealed	N	Y	Y	Y	N	Y	Y
Simple enclosed cab	N	Y	Y	Y	N	Y	Y
No enclosure	Y	Y	Y	Y	Y	Y	Y
Breathing apparatus	Y	N	Y	Y	Y	Y	Y
HEPA filter	Y	N	Y	Y	Y	Y	Y
Simple mask	Y	N	Y	Y	Y	Y	Y
No mask	Y	Y	Y	Y	Y	Y	Y
Organisational measures	Y	Y	Y	N	Y	Y	Y
No organisational measures	Y	Y	Y	Y	Y	Y	Y
General dilution ventilation	N	Y	N	Y	N	Y	Y
No general ventilation	Y	Y	Y	Y	Y	Y	Y

Source: COWI (2019)

2.2. Estimation of the costs of sampling and analysis

The costs of monitoring air concentrations (sampling and analysis) are estimated separately to the core model on the basis of data for several Member States.

The model for costs of sampling and analysis was developed as part of the CMD 3 where information of time used for undertaking the sampling campaign and salary costs in various MS were collected. The model has in this project been updated with information on costs of analysis from an international laboratory. It is assumed that the costs of analysis is the same across the EU, whereas the salaries for undertaking the sampling varies. See detailed tables in COWI (2019)[107].

3. ANALYTICAL CHALLENGES

However, this cost-benefit analyses poses numerous challenges, including:

- Additional health endpoints: when considering the disease burden, only a limited number of cancer and other adverse health effects endpoints have been considered. However, workers may develop additional types of cancer and diseases at higher exposure levels than the doses for the most sensitive endpoints. Those other cancers or adverse health effects, that will be prevented as well, could not be taken into account when calculating in particular the benefits of the proposed OELs, leading to an underestimation of the potential benefits.
- Current number of workers exposed: for some of the substances considered in this impact assessment, the estimated workforce is subject to some uncertainty. This uncertainty could lead to over- or underestimate the number of workers exposed to these substances and impact therefore the cost and benefit estimates.
- Future trends: the exposed workforce and concentration levels are subject to assumptions that vary depending on the substances. For some substances, it is assumed that the exposed workforce and concentrations will remain unchanged over the next 60 years while for other substances, they are assumed to decrease gradually by 2% per year over the same period. It is however very challenging to anticipate the technological and market developments over such a long period. These projected trends in average exposure levels and number of workers exposed may bias the estimated costs and benefits downward or upward.
- Available epidemiologic evidence: the available epidemiologic evidence is scarce and not always sufficiently robust, affecting the reliability of the derived estimates for the number of cancer registrations and deaths. It can therefore be difficult to establish a causal relationship between cancer cases and exposure to a specific carcinogen. Moreover, occupational cancers may develop decades after exposures – including during retirement – complicating the possibility of identifying a causal link. As a result, it is more likely that the health benefits presented in this report could be underestimated.
- Discount rate: in order to allow for comparison between the monetised health benefits and compliance costs, the net present values of the streams of costs and benefits over the 60-year

[107] See footnote 18

period under consideration are computed. The value reported in this impact assessment are calculated on the basis of a static discount rate of 4%. This could lead to underestimate both the costs and benefits in comparison with a dynamic discount rate of 4% for the first 20 years and 3% for the last 40 years.

- Assessment period: the reference period of 60 years was established both to be consistent with the impact assessments for the first three revisions of the CMD and to ensure that the majority of the health benefits are taken into account despite the long latency period for some cancers. It is however likely that some cases of cancer arise after the end of the assessment period and are not be taken into account in this assessment.

4. APPROACH TO THE ASSESSMENT OF THE ENVIRONMENTAL IMPACTS

Potential changes in OELs for the substances considered in this study may subsequently lead to additional or lower environmental impact. Many assumptions, which may or may not be realistic, would have to be included in an analysis of this environmental impact:

- Is the reduction of OELs mainly achieved by increased emissions from ventilation/ exhaust increase?
- Is air emission controlled and reduced, e.g., by filter systems?
- Is removed air integrated into secondary cycles with additional precipitation devices?
- Are filters subsequently disposed or treated (e.g., waste incineration)?
- Are there water screens established to collect and dispose aerosols from workplace?
- What is the link between water screens and effluent water to sewage systems?
- What is the current exact exposure scenario and the status of exposure reduction measures in place?

Because of these heterogeneous parameters, no general and realistic calculation on an environmental impact is possible. Qualitatively, it is assumed that changes in OEL will have limited consequences on environmental exposure and therefore there is only a low-priority need for quantitative consideration within the overall impact assessment.

5. CONSULTATION EXERCISE

This consulation exercice has been developed in annex 2.

6. REACH REGITSRATION DOSSIER /CHEMICAL SAFETY REPORTS (CSRS)

6.1. Identification of the relevant CSRs

In an attempt to gain further insight in current risk management measures and actual exposure levels at workplaces, chemical safety reports (CSRs) submitted under Regulation (EC) No 1907/2006 were assessed. Since CSRs are confidential, ECHA was requested to extract CSRs from registration dossiers for a limited number of 25 substances belonging to the three substances subject to this report (see table 43).

Upon this request, ECHA extracted all files attached in section 13 of the IUCLID (International Uniform Chemical Information Database) datasets of all registrations for these 25 substances. In some cases, these attachments did not represent complete CSRs, but rather other attachments (e.g. files intended to document strictly controlled intermediates for substances registered as intermediates or only part A of the CSR, which typically only contains a statement that RMMs are implemented and communicated). Table 43 lists the substances for which such CSRs were requested and the groups to which they belong.

Table 43: List of substances for which CSRs were requested from ECHA

Substance	CAS No.	Group
Benzene	71-43-2; 1076-43-3	Benzene
Crude oil (petroleum) with recycled naphtha, distilled, cracked, hydrotreated and hydrodesulfurized	1379524-03-4	Benzene
Distillates (petroleum), full-range straight-run middle	68814-87-9	Benzene
Distillates (petroleum), hydrotreated light	64742-47-8	Benzene
Distillates (petroleum), light thermal cracked, debutanized arom.	68955-29-3	Benzene
Fuels, diesel	68334-30-5	Benzene
Gasoline	86290-81-5	Benzene
Kerosine (petroleum)	8008-20-6	Benzene
Ligroine	8032-32-4	Benzene
Naphtha (petroleum), full-range straight-run	64741-42-0	Benzene
Naphtha (petroleum), light catalytic cracked	64741-55-5	Benzene
Naphtha (petroleum), light steam-cracked	64742-83-2	Benzene
Solvent naphtha (petroleum), heavy arom.	64742-94-5	Benzene
Stoddard solvent	8052-41-3	Benzene
Acrylonitrile	107-13-1	Acrylonitrile
Nickle monoxide	1313-99-1	Nickel compounds
Nickel sulphide	16812-54-7	Nickel compounds
Nickel sulphate	7786-81-4; 10101-97-0 10101-98-1	Nickel compounds

Substance	CAS No.	Group
[Carbonato(2-)]tetrahydroxytrinickel	12607-70-4	Nickel compounds
Nickel dichloride	7718-54-9; 7791-20-0	Nickel compounds
Nickel dihydroxide	12054-48-7	Nickel compounds
Nickel dinitrate	13138-45-9; 13478-00-7	Nickel compounds
Trinickel disulphide	12035-72-2	Nickel compounds
Nickel bis(sulphamidate)	547-67-1	Nickel compounds
Nickel di(acetate)	373-02-4; 6018-89-9	Nickel compounds

Source: ECHA - COWI (2019)

Data were extracted in November 2018. All files received from ECHA were evaluated in a secure IT environment.

Under the REACH Regulation, substances can be registered with a full registration (FULL) or an intermediate registration (INT), if the substance is exclusively handled under strictly controlled conditions. In addition, registrations are often submitted by consortia of companies with a single lead company (LEAD) generally submitting the complete CSR and all the members of such a joint submission (MEMBER) often only attaching Part A of the CSR.

6.2. Information of the CSR

While all substances are registered, a registration may or may not contain a complete CSR. Therefore, the attachments extracted by ECHA were further analysed to establish whether these constituted complete CSRs or other files. While the LEAD FULL registration is generally expected to contain the complete CSR, members of a joint submission can chose to submit an additional CSR, e.g. with uses specific to their company or its downstream users that are not covered by the CSR of the lead company. For most of the substances only the LEAD FULL CSR have been extracted; for many of the substance supplemented with a number of appendixes.

The following table summarises the information on CSRs available for evaluation.

Table 44: Availability of CSRs for evaluation

Substance	CAS No.	CSR availability
Benzene	71-43-2; 1076-43-3	4 example CSRs + 2 CSAs
Crude oil (petroleum) with recycled naphtha, distilled, cracked, hydrotreated and hydrodesulfurized	1379524-03-4	No CSRs - CSRs not needed
Distillates (petroleum), full-range straight-run middle	68814-87-9	1 CSR + many appendices

Substance	CAS No.	CSR availability
Distillates (petroleum), hydrotreated light	64742-47-8	2 CSRs. Part A
Distillates (petroleum), light thermal cracked, debutanized arom.	68955-29-3	1 CSR + many appendices
Fuels, diesel	68334-30-5	1 CSR + many appendices
Gasoline	86290-81-5	1 CSR + many appendices
Kerosine (petroleum)	8008-20-6	1 CSR + many appendices
Ligroine	8032-32-4	1 CSR + many appendices
Naphtha (petroleum), full-range straight-run	64741-42-0	1 CSR + many appendices
Naphtha (petroleum), light catalytic cracked	64741-55-5	1 CSR
Naphtha (petroleum), light steam-cracked	64742-83-2	1 CSR
Solvent naphtha (petroleum), heavy arom.	64742-94-5	1 CSR
Stoddard solvent	8052-41-3	1 CSR
Acrylonitrile	107-13-1	1 CSR
Nickle monoxide	1313-99-1	1 CSR
Nickel sulphide	16812-54-7	1 CSR
Nickel sulphate	7786-81-4; 10101-97-0 10101-98-1	1 CSR
[Carbonato(2-)]tetrahydroxytrinickel	12607-70-4	1 CSR
Nickel dichloride	7718-54-9; 7791-20-0	1 CSR
Nickel dihydroxide	12054-48-7	1 CSR
Nickel dinitrate	13138-45-9; 13478-00-7	1 CSR
Trinickel disulphide	12035-72-2	1 CSR
Nickel bis(sulphamidate)	547-67-1	Inactive registration. No CSR
Nickel di(acetate)	373-02-4; 6018-89-9	1 CSR

Source: ECHA - COWI (2019)

The uses of the substance, occupational exposure associated with these uses as well as risk management measures and operational conditions were considered. These data were used in the assessments of the chemical agents documented in the separate substance reports.

Annex 5: National OELs

Acrylonitrile

Table 45: National OELs for acrylonitrile within the EU Member States and other non-EU countries

Member State	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL
Austria[1,5]	4.5 (2.0)[#]	–Sk	18.0 (8.0)	–Sk
Belgium[1,5]	4.4 (2.0)	–Sk	-	
Bulgaria	-		-	
Croatia	-		-	
Cyprus	-		-	
Czech Republic[5]	2.0	–Sk	6.0	–Sk
Denmark[1,5]	4.0 (2.0)		8.0 (4.0)	
Estonia[5]	4.5 (2.0)		13.0 (6.0)	
Finland[1,5]	4.4 (2.0)	–Sk	8.8 (4.0)	–Sk
France[1,5]	4.5 (2.0)		32.5 (15.0)	
Germany[1,2,5]	2.6 (1.2)[§] 0.26 (0.12)[$]	–Sk –Sk	20.8 (9.6)[§] 2.1 (0.96)[$]	–Sk –Sk
Greece[5]	4.5 (2.0)		-	
Hungary[1,3]	4.3	–maximum allowable concentration	-	
Ireland[1,5]	4.5 (2.0)		-	
Italy	-		-	
Latvia[1,5]	0.5		-	
Lithuania[5]	4.5 (2.0)		13.0 (6.0)	
Luxembourg	-		-	
Malta	-		-	
Netherlands	Set by the company		-	
Poland[1,5]	2.0	–Sk	10.0	–Sk
Portugal[5]	4.4 (2.0)		-	

Member State	OEL [mg/m³, (ppm)]	Specification of OEL	STEL [mg/m³, (ppm)]	Specification of STEL
Romania[1,5]	5.0 (2.3)	–Sk	10.0 (4.6)	–Sk
Slovakia[5]	7.0 (3.0)	–Sk	-	–Sk
Slovenia[5]	7.0	–Sk	28.0	–Sk
Spain[1,5]	4.4 (2.0)	–Sk, S	-	
Sweden[1,5]	4.5 (2.0)	–Sk	13.0 (6.0)	–Sk
United Kingdom[1]	4.4 (2.0)	–Sk	-	–Sk
RAC[4]	1.0 (0.45)	–Sk	4.0 (1.8)	–Sk
Non-EU countries				
Australia[1,5]	4.3 (2.0)			
Brazil[6]	35.0 (16.0)		-	
Canada, Ontario[1]	(2.0)		(10.0)	
Canada, Québec[1]	4.3 (2.0)		-	
China[5]	2.0 (0.92)	–maximum allowable concentration	-	
India[7]	4.5 (2.0)	–Sk	-	
Japan[1]	4.3 (2.0)	–Sk	-	
Japan - JSOH[1]	4.3 (2.0)		-	
South Korea[1]	4.5 (2.0)		-	
Switzerland[1]	4.5 (2.0)		-	
USA, ACGIH[5,8]	4.3 (2.0)	–Sk	-	
USA, NIOSH[1,**]	2.2 (1.0)	–Sk	22.0 (10.0)	–Sk
USA, OSHA[1,5]	4.4 (2.0)	–Sk	22.0 (10.0)	–Sk

RAC = Committee for Risk Assessment
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health
Sk = skin notation assigned
- not established/assigned
 # TRK value ("Technische Richtkonzentration", Technical Guidance Concentrations), based on technical feasibility
** classified as C1A and C1B*
† binding limit value
~ restrictive statutory limit value
§ Workplace exposure concentration corresponding to the proposed tolerable cancer risk 4:1,000
$ Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk 4:100,000
+ Reference value corresponding to an individual excess lifetime risk of cancer 10^{-3}
++ Reference value corresponding to an individual excess lifetime risk of cancer 10^{-4}
*** NIOSH indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.*
Data taken from:

1 Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values http://limitvalue.ifa.dguv.de/ accessed on 17.10.2018
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8: ACGIH, American Conference of Governmental Industrial Hygienists (2018), TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Notice of Intended Changes

Table 46: Member states with OELs for acrylonitrile higher than the envisaged scenarios

Target OEL mg/m^3	Member States who would need to introduce or alter legislation	Number of countries required to transpose
0.5	All Member States except Latvia	27
1	All Member States except Latvia	27
2	All Member States except Czech Republic, Poland and Latvia	25
4.5	SK, SL, RO	3

Nickel compounds

Table 47: National OELs for nickel compounds within the EU Member States and other non-EU countries

Country/ Organisation	Soluble inorganic Ni compounds	Insoluble inorganic Ni compounds	Ni metal	Ni compounds	Nickel monoxide	Nickel sulphide	Nickel sulphate	Nickel dichloride	Nickel dihydroxide	Trinickel disulphide	Nickel dioxide	Ni trioxide	Nickel carbonate	Ni matte roasting[‡] or smelting dusts[‡‡]
Austria[1,2,3]	0.05 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	-	0.5 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	0.5 (I)[#] S	-
Belgium[1,2,4]	0.1[*]	0.2[*]	1.0[*]	-	-	1.0[∞,*]	-	-	-	0.1[*]	-	-	-	-
Bulgaria[5]	-	-	0.05[*]	0.05[*]	-	-	-	-	-	-	-	-	-	-
Croatia[6]	0.01[*]	0.05[*]	-	-	-	-	-	-	-	-	-	-	-	-
Cyprus[37]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Czech Republic[37]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Denmark[1,2,7]	0.01[*]	0.05[*]	0.05[*]	-	-	-	-	-	-	-	-	-	-	-
Estonia[37]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Finland[1,2,8]	0.05 (I) 0.01 (R)	0.05 (I) 0.01 (R)	0.01 (R)	-	0.05 (I) 0.01 (R)	0.05 (I) 0.01 (R)	0.05 (I) 0.01 (R)	0.05 (I) 0.01 (R)	0.05 (I) 0.01 (R)	0.05 (I) 0.01 (R)		-	0.05 (I) 0.01 (R)	-
France[1,2,9,###]	-	-	1.0[*]	-	1.0[*]	1.0[*]	0.1[*]	-	1.0[*]	1.0[*]	-	1.0[*]	1.0[*]	1.0[‡,*]
Germany[1,2,10,11]	-	-	0.006 (R)	0.030 (I)	-	-	-	-	-	-	-	-	-	-

				0.013 (R)[$] 0.006 (R)[$] 0.001 (R)[$]										
Greece[37]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hungary[1,2,12]	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	-	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	0.1[M,*] S	-
Ireland[1,2,13]	0.1[*]	0.5[*]	0.5[*] S	-	-	-	-	-	-	-	-	-	-	-
Italy[37]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Latvia[1,2,14]	0.05[*]	0.05[*]	0.05[*]	0.05[*]	0.05[*]	0.05[*]	-	-	-	0.05[*]	0.05[*]	-	-	-
Lithuania[15]	0.1[*] S	-	0.5[*] S	-	0.1[*] S	-	-	-	-	0.01[*]	0.1[*] S	0.01[*]	0.1[*] S	-
Luxembourg[16]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Malta[37]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Netherlands[2,17]	0.1[##,*]	0.1[##,*]	0.1[##,*]	-	-	-	-	-	-	-	-	-	-	-
Poland[9]	-	-	0.25[M,*]	0.25[M,*]	-	-	-	-	-	-	-	-	-	-
Portugal[37]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Romania[1,2,19]			0.1[*]	0.1[*]	-	-	-	-	-	-	-	-	-	-
Slovakia[20]	-	-	0.5 (I) S	0.5 (I)[*] S	0.5 (I) S	0.5 (I) S	-	-	-	-	0.5 (I) S	-	-	-
Slovenia[21]	-	-	0.006 (R) Sk	-	-	-	-	-	-	-	-	-	-	-
Spain[1,2,22]	0.1[*] S	0.2[*] S	1.0[*] S	-	0.1[*] S	0.1[*] S	0.1[*] S	-	0.1[*] S	0.1[*] S	0.1[*] S	-	0.1[*] S	-
Sweden[1,2,23]	-	-	0.5 (T) S	0.1 (T) S	-	-	-	-	-	0.01 (T) S	-	-	-	-
United Kingdom[1,2,24]	0.1[M,*] Sk	0.5[M,*] Sk	0.5[M,*] Sk	-	0.1[M,*] Sk	0.1[M,*] Sk	0.1[M,*] Sk,S	-	-	0.1[M,*] Sk	0.1[M,*] Sk	0.1[M,*] Sk	-	-

RAC[25]	-	-	0.03 (I) S 0.005 (R) S	0.03 (I) S 0.005 (R) S	-	-	-	-	-	-	-	-	-	-
Non-EU countries														
Australia[1,26]	0.1[*] S	-	1.0[*] S	-	-	1.0[*] S	-	0.1[*] ($NiCl_2$)	-	-	-	-	-	-
Brazil[27]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Canada, Ontario[1,28]	0.1 (I)	0.2 (I)	1.0 (I)	-	-	-	0.1 (I)	-	-	0.1 (I)	-	-	-	-
Canada, Québec[1,29]	0.1[*]	1.0[*]	1.0[*]	-	-	-	-	-	-	-	-	-	-	1.0[‡,*]
China[1,30]	0.5[*]	1.0[*]	1.0[*]	-	-	-	-	-	-	-	-	-	-	-
India[31]	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Japan[1]	0.1[+,*]	0.1[+,*]	-	-	-	-	-	-	-	-	-	-	-	-
Japan - JSOH[1,32]	0.01 (T)	0.1 (T)	1.0[*]	-	-	-	-	-	-	-	-	-	-	0.01[++,*] 0.001[+++,*]
South Korea[1]	0.1[*]	0.5[*]	1.0[*]	-	-	1.0[∞,*]	-	-	-	0.1[*]	-	-	-	-
Switzerland[1,2,33]	0.05 (I) S	0.05 (I) S	0.5 (I) S	-	0.05 (I) S	0.05 (I) S	-	-	-	-	-	-	-	-
USA, ACGIH[34]	0.1 (I)	0.2 (I)	1.5 (I)	-	-	-	-	-	-	0.1 (I)	-	-	-	-
USA, NIOSH[1,2,35,***]	0.015[*]	0.015[*]	0.015[*]	-	-	-	-	-	-	0.015[*]	-	-	-	0.015[‡,*]
USA, OSHA[1,2,36]	1.0[*]	1.0[*]	1.0[*]	-	-	-	-	-	-	-	-	-	-	-

RAC = Committee for Risk Assessment
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists

OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health
(I) = inhalable; (R) = respirable; (T) = total dust;
** differentiation in inhalable, respirable or total dust is not made*
S = notation for sensitisation assigned
Sk = skin notation assigned
‡ matte roasting
‡‡ smelting dusts
- no value available
 # TRK value ("Technische Richtkonzentration", Technical Guidance Concentrations), based on technical feasibility
For France indicative limit values (not legally binding) are given.
∞ Nickel sulphide, fume and dust, as Ni, roasting
§ Workplace exposure concentration corresponding to the proposed tolerable cancer risk 4:1,000
$ Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk 4:10,000 (6 µg/m³) or 4:100,000 (1 µg/m³)
Not legally applicable since 01.01.2007
M Maximum exposure limit (MEL) or Maximum Allowable Concentration (MAC)
+ The value is applied to workplaces using powder substances.
++ Reference value corresponding to an individual excess lifetime risk of cancer 10-3
+++ Reference value corresponding to an individual excess lifetime risk of cancer 10-4
**** NIOSH indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.*
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Table 48: Member states with OELs for nickel compounds higher than the envisaged scenarios

OLEV options (inhalable)	MS where current limits are higher	% of MS
0.01 mg/m^3	AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK	89%
0.03 mg/m^3	AT, BE, BG, CY, CZ, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK	86%
0.05 mg/m^3	AT, BE, CY, CZ, EE, EL, ES, FR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SI, SK, UK	75%
0.1 mg/m^3	AT, CY, CZ, EE, EL, FR, IT, LU, MT, PL, PT, SI, SK	46%
0.5 mg/m^3	CY, CZ, EE, EL, FR, IT, LU, MT, PT, SI	36%
1 mg/m^3	CY, CZ, EE, EL, IT, LU, MT, PT, SI	32%

Notes: The actual OELs in each Member State are complex combination of OELs for nickel compounds, specific nickel compounds, soluble nickel compounds and insoluble nickel compounds
Croatia, Denmark and Sweden have OELs for some nickel compounds of 0.01mg/m3

Benzene

Table 49: National OELs for benzene within the EU Member States and other non-EU countries

Member State	OEL mg/m³, (ppm)	Specification of OEL	STEL mg/m³, (ppm)	Specification of STEL
Austria[1,2,3]	3.2 (1.0)[*]	–Sk	12.8 (4.0)[*]	–Sk
Belgium[1,4]	3.25 (1.0)	–Sk	-	
Bulgaria[5]	3.25 (1.0)	–Sk	-	
Croatia[6]	3.25 (1.0)	–Sk	-	
Cyprus	3.25 (1.0)		-	
Czech Republic[2]	3.0		10.0	
Denmark[1,7]	1.6 (0.5)	–Sk	3.2 (1.0)	–Sk
Estonia[2]	1.5 (0.5)		9.0 (3.0)	
Finland[1,2,8]	3.25 (1.0)	–Sk	-	
France[1,2]	3.25 (1.0)[~]	–Sk	-	
Germany[1,2,10]	1.9 (0.6)[§] 0.02 (0.006)[$]	–Sk –Sk	15.2 (4.8)[§]	–Sk
Greece	3.25 (1.0)		-	
Hungary[1,11]	3.0	–maximum allowable concentration	-	
Ireland[1,12]	3.0 (1.0)	–Sk	-	
Italy[1]	3.25 (1.0)	–Sk	-	
Latvia[1,2,13]	3.25 (1.0)	–Sk	-	
Lithuania[2,14]	3.25 (1.0)	–Sk	19.0 (6.0)	–Sk
Luxembourg	3.25 (1.0)		-	
Malta	3.25 (1.0)		-	
Netherlands[1,16]	0.7 (0.2)	–Sk	-	
Poland[1,2,17]	1.6	–Sk	-	
Portugal	3.25 (1.0)		-	
Romania[1,2,18]	3.25 (1.0)	–Sk	-	
Slovakia[2,19]	3.25 (1.0)	–Sk	-	
Slovenia[2,20]	3.25 (1.0)	–Sk	(4.0)	–Sk
Spain[1,2,21]	3.25 (1.0)	–Sk	-	
Sweden[1,2,22]	1.5 (0.5)	–Sk	9.0 (3.0)	–Sk

Member State	OEL mg/m³, (ppm)	Specification of OEL	STEL mg/m³, (ppm)	Specification of STEL
United Kingdom[1,23]	3.25 (1.0)	–Sk	-	
European Union[1,2]	3.25 (1.0)	–Sk	-	
RAC[24]	0.16 (0.05)	-Sk	-	
Non-EU countries				
Australia[25]	3.2 (1.0)		-	
Brazil[26]	-		-	
Canada, Ontario[1,27]	(0.5)	-Sk	(2.5)	-Sk
Canada, Québec[1,28]	3.0 (1.0)		15.5 (5.0)	
China[1,29]	6.0	-Sk	10.0	-Sk
India[30]	1.5 (0.5)		7.5 (2.5)	
Japan[1]	(10)		-	
Japan - JSOH[1,31]	(1.0)[+] (0.1)[++]	-Sk	-	
South Korea[1]	3.0 (1.0)	-Sk	16.0 (5.0)	-Sk
Switzerland[1,32]	1.6 (0.5)	-Sk	-	
USA, ACGIH[33]	1.6 (0.5)	-Sk	8.0 (2.5)	-Sk
USA, NIOSH[1,2,34**]	0.32 (0.1)		3.2 (1.0)	–ceiling limit value (15 min)
USA, OSHA[1,2,35]	3.2 (1.0)		15.0 (5.0)	

RAC = Committee for Risk Assessment
JSOH = Japan Society for Occupational Health
ACGIH = American Conference of Governmental Industrial Hygienists
OSHA = Occupational Safety and Health Administration
NIOSH = National Institute for Occupational Safety and Health
Sk = skin notation assigned
- no value available
** TRK value ("Technische Richtkonzentration", Technical Guidance Concentrations), based on technical feasibility*
~ For France, restrictive statutory limit value given.
§ Workplace exposure concentration corresponding to the proposed tolerable cancer risk 4:1,000
$ Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk 4:100,000
+ Reference value corresponding to an individual excess lifetime risk of cancer 10^{-3}
++ Reference value corresponding to an individual excess lifetime risk of cancer 10^{-4}
*** NIOSH indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.*
Data taken from:

1: Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA) GESTIS– International Limit Values. Available at: http://limitvalue.ifa.dguv.de/, accessed on 17.10.2018
2: ECHA, European Chemicals Agency (2017) Proposal by the European Chemical Agency (ECHA) in support of occupational exposure limit values for benzene in the workplace.
3: October 2017. Available at: https://echa.europa.eu/documents/10162/214b2029-82fd-1656-1910-3e18d0906999, accessed on 18.10.20183:
Austria (2018) Grenzwerteverordnung 2018 – GKV 2018. Available at: https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=20001418, accessed on 27.11.2018
4: Belgium, (2018) List of limit values. Available at: http://www.werk.belgie.be/moduleDefault.aspx?id=1958, accessed on 19.12.2018

5: Bulgaria, (2018) List of limit values. Available at: https://www.lex.bg/laws/ldoc/2135477597, accessed on 30.11.2018
6: Croatia, (2018) List of limit values. Available at: https://narodne-novine.nn.hr/clanci/sluzbeni/2018_10_91_1774.html, accessed on 30.11.2018
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33: ACGIH, American Conference of Governmental Industrial Hygienists (2018), TLVs and BEIs Based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Notice of Intended Changes
34: USA, NIOSH (2018) Pocket Guide to Chemical Hazards. Available at: https://www.cdc.gov/niosh/npg/npgd0049.html, accessed on 27.11.2018
35: USA, OSHA (2018) Occupational Safety and Health Standards 1910.1028. Available at: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10042&p_table=standards, accessed on 27.11.2018
36: no reply received from a contacted person (if possible contact person from a previous EU project was contacted) regarding OELs/STELs

Table 50: Member states with OELs for benzene higher than the envisaged scenarios

OEL (ppm)	MSs where current limits are higher or not identified	% of MSs above reference OELV	Notes
0.05 ppm	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, UK	100%,	DE: Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk 4:100,000: 0.02 ppm
0.2 ppm	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, PL, PT, RO, SE, SI, SK, UK	96%	
0.5 ppm	AT, BE, BG, CY, CZ, EL, ES, FI, FR, HR, HU, IE, IT, LV, LT, LU, MT, PL, PT, RO, SI, SK, UK	82%	
Baseline (1 ppm)	0	0%	

Annex 6: Relevant sectors, uses and activities

1. ACRYLONITRILE

1.1. Relevant sectors, uses and operations

1.1.1. Manufacture of acrylonitrile

Acrylonitrile is manufactured within a closed process via catalytic ammoxidation of ammonia and propylene. This is usually achieved via the Sohio process[108].

During the Sohio process, ammonia and air are passed through a fluidized bed reactor containing a catalyst (bismuth phosphomolybdate). The reactants are then cooled in aqueous sulfuric acid and the excess propylene, carbon monoxide, carbon dioxide and nitrogen are either vented or incinerated. The resulting solution consists of acrylonitrile, acetonitrile, hydrocyanic acid and ammonium sulfate produced from excess ammonia. A recovery column removes water and acrylonitrile and acetonitrile are separated via distillation (IGTPAN website, 2018).

Acrylonitrile is produced within a closed system with very limited exposure expected[109] [110] [111].

1.1.2. Overview of downstream users

Acrylonitrile downstream uses identified can be summarised as follows:

Main uses

- Acrylic and modacrylic textile fibres
- SAN and ABS plastics
- Manufacture of acrylamide and adiponitrile
- Nitrile rubbers
- Carbon fibre

Other uses

- Reagent in a laboratory
- Extraction agents
- Photo-chemicals
- Polyether and polymeric polyols (for the manufacturing of polyurethane flexible foam used to produce mattresses and furniture)
- Carboxylic exchange resins (water treatment);
- Synthesis of amines (Examples include: i) Pesticides, ii) Disinfectants, iii) Housekeeping: Laundry detergent, fabric softener, etc. iv) Personal care: e.g. shower gel);

[108] SCOEL (2003): Recommendation from the Scientific Committee on Occupational Exposure Limits for Acrylonitrile,. Available at: http://ec.europa.eu/social/BlobServlet?docId=6699&langId=en

[109] ECHA [European Chemicals Agency] (2018): Opinion on scientific evaluation of occupational exposure limits for Acrylonitrile. ECHA/RAC/ O-0000001412-86-188/F.
Available at https://echa.europa.eu/documents/10162/13641/acrylonitrile_opinion_en.pdf/102477c9-a961-2c96-5c4d-76fcd856ac19 on 15 January 2019.

[110] ECB [European Chemicals Bureau] (2004): European Union Risk Assessment Report for Acrylonitrile. Report by Institute for Health and Consumer Protection for the European Chemicals Bureau.
Available at https://echa.europa.eu/documents/10162/22bf49d3-e951-44b8-a45a-6973d3dc62f6 on 11 December 2018.

[111] EFTEC, Economics for the Environment, Socio-Economic Analysis: Occupational Exposure Limits for Acrylonitrile, For European Chemical Industry Council (cefic) -Acrylonitrile Sector Group, December 2018 (unpublished)

- Coatings, construction chemicals and adhesives used to glue plastics and rubbers.

According to the RAC's background document on acrylonitrile, 750,000 tonnes of acrylonitrile is manufactured per year within the EU. Similarly, according the Acrylonitrile Sector Group approximately 720,000 tonnes of acrylonitrile are produced in the EU each year, with approximately 129,000 tpa exported to non-EU countries, and 95,000 tpa imported into the EU – resulting in approximately 686,000 tonnes of acrylonitrile being used in the EU each year. The following table provides a breakdown of those tonnages by use, according to the tonnages estimated by RAC and the Acrylonitrile Sector Group.

Table 51 - Tonnage of acrylonitrile used per year according to RAC and the Acrylonitrile Sector Group

Use	Tonnage of acrylonitrile used per year (RAC Background document)	Tonnage of acrylonitrile used per year (Acrylonitrile Sector Group)
Acrylic and modacrylic textile fibres	315,000 (42%)	200,000 (29%)
ABS and SAN plastic resins	179,300 (24%)	184,000 (27%)
Nitrile rubber	53,000 (7%)	45,000 (7%)
Acrylamide	136,000 (18%)	147,000 (21%)
Carbon fibre	Not mentioned	11,000 (2%)
Other	66,700 (9%)	99,000 (14%)

(Source: COWI (2019))

The following table provides an overview of the processes during which acrylonitrile is used.

Table 52 - Processes during which use of acrylonitrile occurs (from ECHA, 2018)

Use	Process(es) during which use occurs
Manufacture of acrylonitrile	Acrylonitrile is manufactured via the Sohio process which is carried out within a closed system.
Production of acrylic and modacrylic textile fibres	The manufacturing process for acrylic fibres comprises four mains steps: i) receiving the monomer into bulk storage, ii) polymerisation iii) spinning, and iv) finishing including drying and baling Local exhaust ventilation (LEV) and personal protection equipment (PPE) are used when not part of a closed system (for spinning and finishing activities)
Production of acrylonitrile-butadiene-styrene (ABS) and styrene-acrylonitrile (SAN) plastics	Production is carried out in a partially closed system, with local exhaust ventilation. Both LEV and PPE are used.
Monomer for production of nitrile rubbers	Acrylonitrile is used as a feedstock in the production of nitrile rubbers. This process is predominantly carried out within a closed system. Both LEV and PPE are used

	when not part of a closed system.
Intermediate for the production of bulk chemicals, resins and adiponitrile/acrylamide synthesis	Acrylonitrile is used as in intermediate to produce acrylamide. Acrylamide is formed via the hydration of acrylonitrile. Adiponitrile is no longer produced in the EU (according to information received from the Acrylonitrile Sector Group via email correspondence)
Laboratory reagent	LEV and PPE are used.

(Source: COWI (2019))

The following table provides an overview of acrylonitrile-based products.

Table 53 - Key acrylonitrile-based products and their uses

Acrylonitrile-based products	Evaluated uses of products
Acrylic and modacrylic textile fibres	These textile fibres absorb little water and are quick drying, although not particularly strong. They can be found in clothing, fake fur, awnings and blankets, among others
Styrene-acrylonitrile resin (SAN)	SAN is a hard transparent and easily processed material. It is used for kitchen equipment such as mixing bowls, fittings for refrigerators, jugs, tableware, and coffee filters
Acrylonitrile-butadienestyrene (ABS) resin	ABS is a material consisting of a two-phase polymer blend. It has a wide range of applications including domestic appliances, telephone handsets, lawnmower covers, safety helmets, luggage shells, pipes and fittings
Nitrile rubbers	Nitrile rubber is oil resistant and its main applications are therefore as seals and connectors for the oil and gas industry. Nitrile rubber is also used for similar reasons by the automotive industry

(Source: COWI (2019))

The sector of use as from the ECHA registrations for acrylonitrile are listed in the following table.

Table 54 - Sectors of use for acrylonitrile listed in the ECHA registrations

Registration	Sector of end use (SU)
Acrylonitrile – Full registration 1 000 000 - 10 000 000 tonnes per annum	SU 0: Other: SU 22: Professional uses
	SU3: Industrial manufacturing
	SU 5: Manufacture of textiles, leather, fur
	SU 8: Manufacture of bulk, large scale chemicals (including petroleum products)
	SU 9: Manufacture of fine chemicals
	SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
	SU 11: Manufacture of rubber products

	SU 12: Manufacture of plastics products, including compounding and conversion
	SU 16: Manufacture of computer, electronic and optical products, electrical equipment
	SU 19: Building and construction work
	SU 20: Health services
	SU 22: Professional use
	SU 24: Scientific research and development

(Source: COWI (2019))

1.2. Exposed workforce

It is important to obtain the number of employees potentially exposed to acrylonitrile in order to calculate the potential benefits of implementing any new measures. The following datasets concerning number of workers exposed to acrylonitrile were identified:

- Carex EU
- Carex Canada
- INRS (The French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases)
- ASA (ASA register (of occupational exposure hazards and procedures in Finland)
- Acrylonitrile Sector Group

The following table summarises the numbers of workers exposed to acrylonitrile according to the different sources of data identified. In some cases the data is not comparable (the sectors do not match or overlapped with other sectors). The sectors have been compared where possible and the final total has been included for each of the datasets. Carex Canada, INRS and ASA figures include both the original and extrapolated EU figures; the extrapolated figures have been adjusted based on population.

Table 55 - Summary of number of workers exposed according to the data sources identified

Sector	Carex EU	Carex Canada	INRS	ASA	Acrylonitrile Sector Group (CEFIC)
Production	Not provided	Not provided	Not provided	Not provided	500
Acrylic fibre	660	Original: 100 EU: 1,396	Not comparable	Not provided	3,750
SAN and ABS resins	8,093	Original: 4,000 EU: 55,854	Not comparable	Original:20 EU: 1,863	1,250

Nitrile Rubber	8,527	Original: 700 EU: 9,774	Original:150–500 EU:1,146–3,819	Not provided	1,750
Acrylamide	7,431	Not provided	Original: 1,500–5,000 EU:	Not comparable	1,000
Carbon fibre	Not provided	Not provided	Not provided	Not provided	250
Other	7,076	Original:1,100 EU: 15,360	Not comparable	Not comparable	1,750
Total	**31,787**	**Original: 5,900** **EU: 82,385**	Original: 5,200–106,919 EU : **40,095–107,683**	Original: 184 EU: **17,139**	**10,250**

(Source: Cowi (2019))

Due to the acrylonitrile industry appearing concentrated in a relatively small number of large companies, it is likely that there will be significant differences between the Member States in terms of numbers of workers exposed. The data sources that have been compiled at EU levels have therefore been selected, providing an upper and a lower estimate for the exposed workforce.

1.2.1. The low and high estimates taken for exposed workforce

Based on the Carex EU and the Acrylonitrile Sector Group data, the number of exposed workers is estimated to be approximately 10,000–33,000 workers.

The Carex EU data are relatively old (1999) and have therefore been converted to 2016 figures based on population data taken from Eurostat. The Carex EU data are considered to provide a higher estimate as they are based on figures of potentially exposed workers (which includes some workers unlikely to be exposed).

The following table summarises the numbers of workers exposed to acrylonitrile for each sector according to these two sources of data.

Table 56 - Summary number of exposed workers per sector according to the Acrylonitrile Sector Group and Carex EU data

Sector	Acrylonitrile Sector Group (CEFIC)	Carex EU (converted to 2016)
Production	500	Not provided
Acrylic fibre	3,750	692
SAN and ABS resins	1,250	8,487
Nitrile Rubber	1,750	8,942
Acrylamide	1,000	7,793
Carbon fibre	250	Not provided
Other	1,750	7,421
Total	**10,250**	**33,335**

The data taken from the Acrylonitrile Sector Group's SEA are the lower of two sets of estimates provided within the SEA itself, and are based on the direct number of persons employed within the industry. An indirect number has also been provided in the SEA, but the direct numbers have been chosen so as to represent the lowest possible estimate. The direct numbers include those employed by the two manufacturers of acrylonitrile plus those employed by the initial downstream users of acrylonitrile.

During consultation it was also indicated that acrylonitrile storage facilities are located within the EU. It has been estimated, based on the data provided in consultation, and via literature reviews, that approximately 10 storage sites could be present within the EU. The numbers of workers exposed within this sector are not expected to be high, and so the estimates provided by the Acrylonitrile Sector Group and Carex EU will remain the same once rounded (10,000–33,000). 'Storage' has been added as a sector for the analysis of the costs and benefits (see Market Analysis).

1.2.2. Trends

Demand in acrylic fibres has decreased due to competition from the cheaper polyester fibres. This is likely to have resulted in a decline in the number of workers exposed to acrylonitrile in this sector since 2000[112].

The numbers of those working within the ABS plastics industry are however expected to have increased due to growing demand for these lightweight materials within new technology such as automobiles and 3D printing applications[113].

The nitrile rubber market has also experienced some growth due to increased production of nitrile gloves[114].

112 IHS Markit (2017): 'Acrylonitrile – Chemical Economics Handbook', accessed on 16/01/19 at: https://ihsmarkit.com/products/acrylonitrile-chemical-economics-handbook.html

113 Mordor Intelligence (2018): 'Global Acrylonitrile Market – Segmented by End-user Industry and Geography – Growth, Trends and Forecast (2019–2024), accessed on 16/01/19 at: https://www.mordorintelligence.com/industry-reports/global-acrylonitrile-acn-market-industry

The exact rate at which the workforce has grown is not known, however based on the above qualitative data it is assumed that size of the workforce is likely to be constant.

1.2.3. *Exposed workers: conclusion*

The data collected through consultation for this study provides evidence of around 10,250 to 33,335 workers currently exposed to acrylonitrile. It is important to note that the upper estimate is likely to include some workers that would not be directly exposed to acrylonitrile, while the lower estimate only takes into account the direct number of workers exposed (i.e. those employed by the 2 manufacturers of acrylonitrile and the initial downstream users).

Table 57 - Exposed workforce: conclusion

Estimate	No of exposed workers
Highest estimate	33,335
Lowest estimate	10,250
Estimate taken forward for modelling	10,000-33,000
Alternative estimate for the sensitivity analysis	Taken into account in the range above
Annual rate of change taken forward for modelling	0% (past and future)

2. NICKEL COMPOUNDS

2.1. Relevant sectors, uses and operations

2.1.1. *Overview of uses and manufacturing processes*

A wide variety of nickel compounds occur in intermediate use, such as[115]:

- Nickel chloride and nickel hydroxide are used catalysts in the metallurgic industry.
- Nickel acetate and nickel sulphate are used to manufacture catalysts and other nickel compounds.
- Trinickel disulphide is used as an intermediate in the primary nickel industry.

The manufacturing processes (PROCs) relating to nickel compounds under the CMD in REACH registration dossiers is shown in table 58 below.

[114] See footnote 18

[115] IARC (2012), Nickel and nickel compounds (updated 26 July 2017) IARC monographs on the evaluation of carcinogenic risks of chemicals to humans, vol. 100C. Available at: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100C-10.pdf.

Table 58 – Nickel compounds and their PROCs according to REACH dossiers[116]

Process	Nickel monoxide	Nickel sulphide	Nickel sulphate	[Carbonato(2-	Nickel dichloride	Nickel dihydroxide	Nickel dinitrate	Trinickel disulphide	Nickel bis(sulphamidate)	Nickel di(acetate)
PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 4: Chemical production where opportunity for exposure arises	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 5: Mixing or blending in batch processes	✓		✓	✓	✓	✓	✓		✓	✓
PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
PROC 10: Roller application or brushing		✓	✓	✓	✓	✓			✓	✓
PROC 11: Non-industrial spraying							✓			
PROC 13: Treatment of articles by dipping and pouring	✓		✓	✓	✓	✓	✓		✓	✓
PROC 14: Tabletting, compression, extrusion, pelletisation, granulation	✓	✓	✓	✓		✓	✓	✓		
PROC 15: Use as laboratory reagent	✓	✓	✓	✓	✓		✓	✓	✓	✓
PROC 19: Hand-mixing with intimate contact and only PPE available	✓									
PROC 21: Low energy manipulation of substances bound in materials and/or articles	✓		✓			✓	✓			
PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting	✓	✓	✓	✓	✓	✓	✓	✓		

[116] ECHA (2018), "*Background document in support of the Committee for Risk Assessment (RAC) for evaluation of limit values for nickel and its compounds in the workplace*". ECHA/RAC/O-0000001412-86-189/F. Available at: https://echa.europa.eu/documents/10162/13641/nickel_bg_annex1_en.pdf/12d24cbf-8f7e-0f1f-64c3-4992df4d00e8

Process	Nickel monoxide	Nickel sulphide	Nickel sulphate	[Carbonato(2-	Nickel dichloride	Nickel dihydroxide	Nickel dinitrate	Trinickel disulphide	Nickel bis(sulphamidate)	Nickel di(acetate)
PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature	✓									
PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles	✓		✓	✓		✓				
PROC 25: Other hot work operations with metals	✓					✓				
PROC 26: Handling of solid inorganic substances at ambient temperature	✓	✓	✓	✓	✓	✓	✓		✓	✓
PROC 27a: Production of metal powders (hot processes)	✓									
PROC 28: Manual maintenance (cleaning and repair) of machinery	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

2.1.2. Overview of sectors

The COWI study identified the following industrial sectors as using nickel compounds under the CMD and having employees at risk of exposure to nickel compounds.

Table 59 – Sectors using nickel compounds under the CMD

NACE	Name	Consultation (5)	CSRs	NI sector	REACH SU	RAC	IARC 2012 NIOSH USA (1)	IARC 2012 CAREX EU (2)	EU RAR	CAREX EU	ASA (4)	INRS	SUMER	Hughson	IOM	Kendzia	BGAA	DGUV	Scarselli	Scarselli
Type of data (3)		W, E	E		M	M	W	W	M	W	W	E	W	E	E	E	E	E	E	W
Year		2019	2018	2018	2019	2018	1981-1983	1990-1993	2008	1990 -1993 & 1997	2014	1987 - 2018	2003 & 2010	2010	2008	2017	2000	2014	2018	2018
A	Agriculture, biogas production		Y		Y							Y								
A7	Mining of metal ores							Y		Y										
C10	Manufacture of food products									Y									Y	
C13.99	Manufacture of other textiles n.e.c.									Y		Y								
C19.2	Manufacture of refined petroleum products (using catalysts)		Y	Y	Y	Y				Y	Y								Y	Y
C20.12	Manufacture of dyes and pigments		Y	Y		Y			Y											
C20.13	Manufacture of other inorganic basic chemicals		Y	Y	Y				Y	Y	Y					Y		Y	Y	
C20.30	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	Y																		

NACE	Name	Consultation (5)	CSRs	NI sector	REACH SU	RAC	IARC 2012 NIOSH USA (1)	IARC 2012 CAREX EU (2)	EU RAR	CAREX EU	ASA (4)	INRS	SUMER	Hughson	IOM	Kendzia	BGAA	DGUV	Scarselli	Scarselli
Type of data (3)		W, E	E		M	M	W	W	M	W	W	E	W	E	E	E	E	E	E	W
Year		2019	2018	2018	2019	2018	1981-1983	1990-1993	2008	1990 -1993 & 1997	2014	1987 - 2018	2003 & 2010	2010	2008	2017	2000	2014	2018	2018
C20.59	Manufacture of other chemical products n.e.c. (inc catalysts)		Y	Y		Y			Y											Y
C21.1	Manufacture of basic pharmaceutical products	Y																		Y
C22	Manufacture of rubber and plastic products									Y									Y	
C23	Manufacture of other non-metallic mineral products		Y		Y					Y	Y	Y				Y				Y
C23.91	Production of abrasive products	Y																		
C24	Manufacture of basic metals				Y	Y	Y	Y	Y	Y	Y	Y	Y			Y	Y		Y	Y
C24.1	Manufacture of basic iron and steel and of ferro-alloys		Y	Y										Y						
C24.41	Precious metals production	Y																		
C24.43	Lead, zinc and tin production	Y													Y					

NACE	Name	Consultation (5)	CSRs	NI sector	REACH SU	RAC	IARC 2012 NIOSH USA (1)	IARC 2012 CAREX EU (2)	EU RAR	CAREX EU	ASA (4)	INRS	SUMER	Hughson	IOM	Kendzia	BGAA	DGUV	Scarselli	Scarselli
Type of data (3)		W, E	E		M	M	W	W	M	W	W	E	W	E	E	E	E	E	E	W
Year		2019	2018	2018	2019	2018	1981-1983	1990-1993	2008	1990 -1993 & 1997	2014	1987 - 2018	2003 & 2010	2010	2008	2017	2000	2014	2018	2018
C24.45	Other non-ferrous metal production	Y																		
C25	Manufacture of fabricated metal products, except machinery and equipment				Y		Y	Y	Y	Y	Y	Y	Y						Y	Y
C25.29	Manufacture of other tanks, reservoirs and containers of metal																			Y
C25.4	Manufacture of weapons and ammunition																			Y
C25.5	Forging, pressing, stamping and roll-forming of metal; powder metallurgy																			Y
C25.61	Treatment and coating of metals	Y	Y	Y		Y			Y					Y	Y	Y	Y			Y
C25.73	Manufacture of tools	Y																		
C25.99	Manufacture of other fabricated metal products n.e.c																			Y
C26	Manufacture of computer, electronic and optical products		Y		Y					Y									Y	Y

NACE	Name	Consultation (5)	CSRs	NI sector	REACH SU	RAC	IARC 2012 NIOSH USA (1)	IARC 2012 CAREX EU (2)	EU RAR	CAREX EU	ASA (4)	INRS	SUMER	Hughson	IOM	Kendzia	BGAA	DGUV	Scarselli	Scarselli
Type of data (3)		**W, E**	**E**		**M**	**M**	**W**	**W**	**M**	**W**	**W**	**E**	**W**	**E**	**E**	**E**	**E**	**E**	**E**	**W**
Year		**2019**	**2018**	**2018**	**2019**	**2018**	**1981-1983**	**1990-1993**	**2008**	**1990 -1993 & 1997**	**2014**	**1987 - 2018**	**2003 & 2010**	**2010**	**2008**	**2017**	**2000**	**2014**	**2018**	**2018**
C27	Manufacture of electrical equipment									Y	Y	Y	Y						Y	
C27.2	Manufacture of batteries and accumulators	Y	Y	Y		Y			Y							Y	Y			
C28	Manufacture of machinery and equipment n.e.c.	Y		Y	Y		Y	Y		Y	Y	Y	Y						Y	Y
C29	Manufacture of motor vehicles, trailers and semi-trailers						Y	Y				Y							Y	
C30	Manufacture of other transport equipment						Y	Y		Y		Y							Y	Y
C31	Manufacture of furniture									Y		Y							Y	Y
C32	Other manufacturing											Y								
C33	Repair and installation of machinery and equipment						Y					Y								Y
C37	Sewerage																		Y	
E38.3	Materials recovery										Y	Y				Y	Y		Y	Y

NACE	Name	Consultation (5)	CSRs	NI sector	REACH SU	RAC	IARC 2012 NIOSH USA (1)	IARC 2012 CAREX EU (2)	EU RAR	CAREX EU	ASA (4)	INRS	SUMER	Hughson	IOM	Kendzia	BGAA	DGUV	Scarselli	Scarselli
Type of data (3)		W, E	E		M	M	W	W	M	W	W	E	W	E	E	E	E	E	E	W
Year		2019	2018	2018	2019	2018	1981-1983	1990-1993	2008	1990 -1993 & 1997	2014	1987 -2018	2003 & 2010	2010	2008	2017	2000	2014	2018	2018
F	Construction									Y		Y							Y	
M71	Architectural and engineering activities; technical testing and analysis										Y	Y							Y	
M72	Scientific research and development				Y						Y	Y	Y						Y	
	Welding													Y (5)		Y	Y			
	Plus				A,	(6)				(7)	P85	(8)								

Sources: RAC (2018a), EU RAR (2008), CAREX (undated), ASA (2014, IARC (2012), IARC (2018), SUMER (2010), IOM (2008), Hughson (2009), Kendzia (2017), BGAA (2000), Scarselli (2018), CSRs (confidential) and consultation responses (confidential)

Notes 1 60% of exposed workers in sectors below

2 83% of exposed workers in sectors below

3 W = workers, E = exposure, M = mention

4 Sectors with over 100 workers exposed

5 Plus several more papers listed in Table 1.9 of IARC (2018)

6 Slags, ferronickel manufacturing (RAC, 2018a)

7 NACE codes: B6, C11, C13, C14, C15, C16, C17, C18, D35, H49, I, Q, M75, S96

*8 Several sectors see Appendix **Error! Reference source not found.***

The table below shows the percentage of enterprises in key sector that are small, medium or large sized enterprises. It is based upon the proportions for small, medium and large from Eurostat data for enterprises at the NACE code.

Table 60 - Distribution of EU enterprises with exposed workers by size of enterprise by sector

NACE	Sector	Number of enterprises			
	Sector	Small <50 employees	Medium 50-249 employees	Large >249 employees	Total
C19.2 Oil refineries		856	76	87	1,019
C20.12 Pigments		0	2	9	11
C20.30 Frits		0	10	40	50
C20.59 Catalysts		28	56	56	140
C23 Glass		1,069	50	17	1,136
C24 Metals		100	123	147	370
C25.61 Metal surface treatment		27,694	759	84	28,536
C25.61 Beyond		27,694	759	84	28,536
C27.2 Batteries		0	6	4	10
E38.3 Materials recovery		1,925	55	20	2,000
Welding		51	100	100	251
Total		**59,417**	**1,996**	**648**	**62,059**

Source: Eurostat (2016), consultation

2.1.3. Overview of sectors

Table 61 - Nickel compounds under the CMD – summary of past exposure (inhalable) concentrations for analysis (1990 – present day)

Sector	Exposure at percentile (mg/m^3)				
	50	75	90	95	100
C19.2 Oil refineries	0.03	0.03	*0.07*	*0.09*	*0.1*
C20.12 Pigments	*0.024*	0.03	*0.043*	*0.046*	0.05
C20.30 Frits	0.014	0.03	*0.053*	*0.06*	0.067

Sector	Exposure at percentile (mg/m^3)				
	50	75	90	95	100
C20.59 Catalysts	0.011	0.03	*0.045*	0.05	0.343
C23 Glass	0.01	0.04	0.19	0.45	*0.696*
C24 Metals	0.04	0.08	0.2	0.61	2.78
C25.61 Metal surface treatment	0.098	0.23	0.8	1.1	*1.384*
C25.61 Beyond	0.098	0.23	0.8	1.1	*1.384*
C27.2 Batteries	0.03	0.13	0.37	0.57	*0.76*
E38.3 Materials recovery	0.014	*0.01*	0.05	0.12	*0.186*
Welding	0.02	*0.0386*	0.25	0.42	0.65

Table 62 - Nickel compounds under the CMD – summary of current exposure concentrations (inhalable) for analysis 2010 to present day

NACE	Sector	Exposure at percentile (mg/m^3)				
		50	75	90	95	100
C19.2 Oil refineries		0.03	0.03	*0.07*	*0.09*	*0.1*
C20.12 Pigments		*0.024*	0.03	*0.043*	*0.046*	0.05
C20.30 Frits		0.014	0.03	*0.053*	*0.06*	0.067
C20.59 Catalysts		0.011	0.03	*0.045*	0.05	0.343
C23 Glass		0.004	0.03	*0.043*	*0.046*	0.05
C24 Metals		0.033	*0.04*	*0.144*	0.175	0.27
C25.61 Metal surface treatment		0.03	*0.04*	*0.149*	0.181	0.25
C25.61 Beyond		0.03	*0.04*	*0.149*	0.181	0.25
C27.2 Batteries		0.012	0.03	*0.045*	0.05	0.2
E38.3 Materials recovery		0.0003	0.002	*0.0028*	*0.003*	*0.0032*
Welding		0.004	0.02	0.05	*0.084*	0.116

2.2. Exposed workforce

COWI study evalutates the number of exposed workers to nickel compounds under the scope of the CMD, by taking into account several sources of information. Further information can be found in this study[117].

The study consultation response gave some detailed responses about the number of workers exposed on a given site and the total number of workers at a site. Only sectors where at least three respondents provided the data are included. Overall, the average number of exposed workers in a company using nickel compounds is 9.6%. Generally, if no other data is available, the study team assumes that 10% of workers in an enterprise using nickel compounds will be exposed to them.

Table 63 – Percentage of exposed workers in company using nickel compounds under the scope of the CMD, from the consultation survey

NACE	Sector	% of exposed workers
C20.30	Manufacture of paints and coatings (frits)	13%
C20.59	Manufacture of other chemical products (catalysts)	3%
C24	Manufacture of basic metals and alloys	32%
C25	Treatment and coating of metals	7%
C27.2	Manufacture of batteries and accumulators	22%

Based on all this information, the study team's estimates are the following:

Table 64 – Summary of extrapolation of EU workers exposed to nickel compounds under the CMD in key sectors

NACE	Sector	Total number of workers in this NACE code (2016)	Study team estimate of exposed workers	% of all workers in NACE code
C19.2 Oil refineries		122,962	6,148	5%
C20.12 Pigments		30,146	230	0.8%
C20.30 Frits		150,157	500	0.3%

[117] See footnote 18

NACE	Sector	Total number of workers in this NACE code (2016)	Study team estimate of exposed workers	% of all workers in NACE code
C20.59 Catalysts		131,047	4,000	3%
C23 Glass		247,487	2,361	1%
C24 Metals		400,825	5,840	1.3%
C25.61 Metal surface treatment		1,269,547	31,099	2.4%
C25.61 Beyond		NA	31,099	NA
C27.2 Batteries		26,328	500	2%
Welding		NA	3,100	NA
E38.3 Materials recovery		174,068	2,611	1%
Total		**2,552,567**	**87,488**	**NA**

2.2.1. Comparison of workers exposed from different sources

In table 65, the estimates from the four sources are compared for all sectors and welding is also included. Data is also available from the SUMER database[118] but cannot easily be allocated to the sectors. The total estimated number of exposed workers is 713,201. A further estimate is available from the CAREX estimates in Spain done in 2004[119] and this estimates that 90,964 workers are exposed to nickel metal and nickel compounds in Spain, which extrapolates to 909,927 workers across the EU. Estimates from ASA, CAREX and SUMER include workers exposed to nickel metal as well as nickel compounds.

The study team's estimates are used for the remainder of the analysis because the estimates based upon the ASA and CAREX data includes many workers exposed to nickel metal; this study is specifically only concerned about workers exposed to nickel compounds. These numbers would be a significant overestimate of the number of workers exposed to nickel compounds. The estimates based upon Scarselli data are believed to be underestimates as not all Italian companies using carcinogenic materials are registered on SIREP.

[118] SUMER (2010): Les expositions aux risques professionnels. Les produits chimiques. *SUMER*.
[119] CAREX (2004): Information System about Occupational Exposure to Carcinogens in Spain in the year 2004 http://istas.net/descargas/InformeCarex.pdf.

Table 65 – Summary of estimated number of EU workers exposed to nickel compounds under the CMD in key sectors

NACE	Sector	ASA 2014[120]	CAREX 1999[121]	Scarselli 2018[122]	Study team estimates Eurostat, survey and industry data, 2019
		Exposure to nickel metal and compounds		Exposure to nickel compounds only	
C19.2	Oil refineries	462	400	3,227	6,148
C20	Manufacture of chemicals and chemical products	28,082	13,072	2,326	4,730
C23	Manufacture of other non-metallic mineral products	6,858	5,279	864	2,361
C24	Manufacture of basic metals	75,485	58,672	470	5,840
C25	Manufacture of fabricated metal products, except machinery	137,270	195,597	13,761	31,099
Beyond C25	C10, C21, C22, C16, C27, C28, C29, C30, C31, C31, F43, M72	213,584	219,428	11,351	31,099
C27.2	Manufacture of batteries and accumulators	-		-	500
E38.3	Materials recovery	21,106	-	1,216	2,611
NA	Welding	NA	NA	NA	3,100
TOTAL		**482,847**	**492,448**	**33,215**	**87,488**

2.2.2. *Exposed workers of reproductive age*

One of the non-cancer outcomes is reprotoxic effects and these apply to both women of reproductive age (15 – 50 years) and to the partners of men of reproductive age (all ages). Therefore, the numbers of exposed workers need to be multiplied by this percentage before

[120] ASA (2014), ASA 2014 Syöpäsairauden vaaraa aiheuttaville aineille ja menetelmille ammatissaan altistuneiksi ilmoitetut Suomessa. *TYÖTERVEYSLAITOS HELSINKI*. Available at: http://www.julkari.fi/handle/10024/131073.

[121] CAREX (1999): International Information System on Occupational Exposure to Carcinogens. *CAREX*. Available at: https://www.ttl.fi/wp-content/uploads/2018/01/EU_5_exposures_by_agent_and_industry.pdf

[122] Scarselli, Alberto, Di Mazio, Davide, Marinaccio, Alessandro, Lavicoli, Sergio (2018): Nickel compounds in the workplaces: Occupations and activities involving high-risk exposures in Italy. *Am J Ind Med*, 61 (12), pp 968-977. Available at https://www.ncbi.nlm.nih.gov/pubmed/30352130

calculating the cases of reprotoxic outcomes. The average percentage of workers of reproductive age for the key sectors is shown in table 66.

Table 66 – Percentage of exposed workers of reproductive age

NACE	Sector	% of reproductive age (1)
C19.2	Manufacture of refined petroleum products	94%
C20.12	Manufacture of dyes and pigments	92%
C20.30	Manufacture of paints and coatings	92%
C20.59	Manufacture of other chemical products	92%
C23	Manufacture of other non-metallic mineral products	93%
C24	Manufacture of basic metals	96%
C25	Treatment and coating of metals	95%
C27.2	Manufacture of batteries and accumulators	92%
E38.3	Materials recovery	95%
NA	Welding[123]	95%

2.2.3. Exposed workers: conclusion

Table 67 – Estimated number of EU workers exposed to nickel compounds under the CMD in key sectors

The data collected through consultation for this study provides evidence of approximately 87,488 workers currently exposed to nickel compounds under the CMD.

Sector		Estimated exposed workers
C19.2 Oil refineries		6,148
C20.12 Pigments		230
C20.30 Frits		500
C20.59 Catalysts		4,000
C23 Glass		2,361
C24 Metals		5,840
C25.61 Metal surface treatment		31,099
C25.61 Beyond		31,099

[123] Welding is an average of the other sectors.

Sector		Estimated exposed workers
C27.2 Batteries		500
E38.3 Materials recovery		2,611
Welding		3,100
Total		**87,488**

3. BENZENE

3.1. Relevant sectors, uses and operations

3.1.1. Manufacture of benzene

Benzene is produced in petroleum refinery and chemical plant processes, primarily by catalytic reforming, steam cracking and dealkylation. Benzene can also be recovered during production of coal-derived chemicals, primarily from coke oven by-products. It is extracted from these sources and purified for industrial use. Benzene is manufactured and/or imported in the European Economic Area in a quantity of 1,000,000 to 10,000,000 tonnes per year. Under REACH, the registered substance reporting "benzene" as its substance identity has been registered mainly as transported isolated intermediate or onsite isolated intermediate[124]. Petrochemicals Europe state that the European production of benzene is about 8 million tons/year[125]

The typical feedstocks to catalytic reformer units are the hydrotreated straight-run heavy naphtha from crude oil distillation units and, if applicable, the hydrotreated heavy naphtha stream from hydrocracker units or coking units, as well as medium catalytically cracked naphtha stream from a FCC (fluid catalytic cracking) unit. Products from a reformer include, in addition to the hydrogen: refinery fuel gas, LPG, isobutene; n-butane and reformate. The reformate contains benzene and may be blended into petrol[126] or further separated into its components as chemical feedstocks (benzene, toluene, xylene, and naphtha cracker feeds)[127].

In the lower olefins sector[128], *steam cracking processes* produce pyrolysis gasoline, which contains benzene and other aromatics. Pyrolysis gasoline (also called pygas) constitutes about 60% of the feedstock for aromatics plants, which produce benzene as well as other aromatics by extraction with a purity of up to 99.9%. Alternatively, pyrolysis gasoline is blended with other

[124] See footnote 22

[125] European Market overview data available from: https://www.petrochemistry.eu/about-petrochemistry/petrochemicals-facts-and-figures/european-market-overview/

[126] Please note that usually the British English term 'petrol' is used, while 'gasoline' (Am. English) is only used when required by context. However, 'petrol' and 'gasoline' denote the type of petroleum-derived liquid.

[127] Best Available Techniques (BAT) Reference Document (2015), BAT Reference Document for the Refining of Mineral Oil and Gas. Available at: https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/best-available-techniques-bat-reference-document-refining-mineral-oil-and-gas-industrial.

[128] Olefins (= alkenes), such as ethylene, are produced by steam cracking aliphatic hydrocarbons.

hydrocarbons to produce petrol. The remaining 40% of feedstock for aromatics plants is derived from refineries and coal chemistry streams[129].

Benzene is also formed during coking of coal. Benzene and other aromatics are present in the coke oven gas and are recovered as by-products from the coking process.

3.1.2. Overview of the sectors

The RAC background document[130] summarises in table 68 below work areas/sectors where occupational exposures to benzene have been measured. This table has been supplemented with data from further publications as well as information received during stakeholder consultation.

The table 68 shows that exposure to benzene occurs and/or has historically occurred in up to 15 sectors and in many occupational settings. Some activities, such as tank maintenance and cleaning, and loading/unloading of benzene-containing streams, are relevant for numerous sectors. The study devotes most attention to the sectors where occupational exposure is likely to be a significant issue based on exposure concentrations, number of workers exposed and trends in exposure. The table 69 list the relevant NACE-codes for the sector

Table 68 - Work areas with occupational exposures to benzene

[129] LOA (2018), Detailed comments on the ECHA proposal for benzene workplace OEL values. Embeded in Benzene Annex 2 of the RACT (2018) opinion available at: https://echa.europa.eu/da/about-us/who-we-are/committee-for-risk-assessment/opinions-of-the-rac-adopted-under-specific-echa-s-executive-director-requests

[130] See footnote 22

No.	Sector	Description / scope in current study	Presence of benzene	Examples of activities/ occupations/ exposure situations/	Source
1	Upstream petroleum industry	Crude oil production Natural gas production	Benzene is a natural component of crude oil and natural gas/natural gas liquids. The benzene content in crude oil differs between the oil fields. As examples, a content of 0.52% for an oilfield in the North Sea has been reported. Crude oil assays from different regions on the Norwegian continental shelf (n=14) showed a mean and median value of 0.28% benzene by weight (range <0.01–0.66%).	Repair, maintenance and exchange of valves, pumps Maintenance work during turnaround Tank maintenance and cleaning Natural gas condensate loading Sampling	RAC, 2018a; stakeholder consultation; (Kirkeleit et al., 2006)
2	Downstream petroleum industry	Refineries (processing crude oil and natural gas) Steam crackers Aromatics extraction units Manufacturers of refined petroleum products	Benzene is present in certain streams of refining and steam cracking output products (naphtha and pyrolysis gasoline). Benzene is extracted from benzene containing streams.	Repair, maintenance and exchange of valves, pumps Maintenance work during turnaround Tank maintenance and cleaning Loading and unloading of benzene or benzene containing streams, e.g. naphtha, petrol Sampling Fugitive emissions	RAC, 2018a; ECHA 2017a; HVBG, 2002
3	Coking plants	Coking plants are often located in vicinity to sites of iron and steel production. Coke is used as metallurgical coke in blast furnaces for metal smelting or for heating. To a lesser extent, coke is produced for heating purposes.	Benzene is a by-product in the coking of hard coal. Benzene is recovered from coke oven gas and tar.	Maintenance work on the coke oven battery Maintenance work in the by-product plant Fugitive emissions	RAC, 2018a, HVBG, 2002; stakeholder consultation
4	Petrochemical	Chemical manufacturers use benzene as	Pure benzene is used as a raw material for manufacture of	Tank maintenance and cleaning	RAC, 2018a; stakeholder

No.	Sector	Description / scope in current study	Presence of benzene	Examples of activities/ occupations/ exposure situations/	Source
	industry	intermediate in the production of basic chemicals such as ethylbenzene, cumene, cyclohexane, nitrobenzene, alkylbenzene and others derivatives. Ethylbenzene accounts for almost half of the benzene intermediate consumption. These substances are further used for the manufacture of plastics, synthetic rubber, dyestuffs, resins, raw materials for detergents, and plant protection agents. In some respects, steam crackers or aromatics extraction plants are considered as petrochemical industry. However, in the current assessment, these users of benzene-containing streams are considered in the downstream petroleum sector.	basic chemicals	Styrene production Loading and unloading of benzene Sampling Fugitive emissions	consultation
5	Distribution	Distribution of benzene, petrol and benzene-containing streams from manufactures via bulk storage sites to users by means of road, rail and ship transport.	Benzene, petrol and benzene-containing streams	Tank maintenance and cleaning Tank filling Sampling Road tanker driver	RAC, 2018a; HVBG, 2002; stakeholder consultation
6	Retail and petrol stations	Sale of fuels to consumers and professionals	Benzene may be contained up to 1% v/v in petrol as an anti-knocking agent. Before 2000, the concentration of benzene in petrol was usually 2% or higher.	Filling assistants at petrol stations (primarily Southern Europe) Pump calibration and maintenance	DGUV, 2018; stakeholder consultation
7	Maintenance and	Repairing workshops for cars, ships,	Benzene may contained up to 1% v/v in petrol.	Use of petroleum-based	RAC, 2018a;

No.	Sector	Description / scope in current study	Presence of benzene	Examples of activities/ occupations/ exposure situations/	Source
	repair of motor vehicles	airplanes and other vehicles	Petroleum-based products containing benzene.	products Tank filling	HVBG, 2002; Breuer et al., 2015
8	Foundries	Casting and moulding	Benzene may be formed and emitted during pyrolysis of organic binders	Sand plant Casting	BGIA 2009, stakeholder consultation
9	Several sectors	Exposure to benzene from exhaust of vehicles/equipment	Benzene is formed during incomplete combustion processes, e.g. petrol combustion	Traffic policeman Filling assistants at petrol stations (primarily Southern Europe) Landscape and forestry workers using petrol-engined equipment Taxi drivers	RAC, 2018a; Breuer et al., 2015
10	Laboratories - Research, development and education	Within the petroleum/petrochemical industry, sampling and analysis of benzene-containing streams is an integrated part of the business. Small quantities of benzene are used as a laboratory reagent and solvent. This use is declining, however, benzene does occur in small quantities in various solvents on a hydrocarbon basis	Benzene may be used as a solvent or be present in samples	Lab technician	RAC, 2018a EU RAR, 2008
11-15	Other sectors	Printing industry Shoe manufacture	Petroleum-based products containing benzene as a solvent or as impurity, e.g. lacquers, paints, glues, inks.	Historically relevant, present exposures in EU significantly reduced/ not present:	RAC, 2018a; Armold et al., 2013

No.	Sector	Description / scope in current study	Presence of benzene	Examples of activities/ occupations/ exposure situations/	Source
		Service sector Rubber manufacture and surface treatment Manufacture of artificial leather		Surface cleaning with petroleum solvents Painting with lacquer Various printing operations Use of mineral spirits (spray cleaning and degreasing)	

Table 69 - Relevant NACE codes for key sectors

Sector	NACE code
Upstream petroleum industry	B 6.1 Extraction of crude petroleum
Downstream petroleum industry: Refineries	C 19.2 Manufacture of refined petroleum products (partly)
Coking plants	C 19.1 Manufacture of coke oven products
Petrochemical industry	C 20.14 Manufacture of other organic basic chemicals (partly) C 19.2 Manufacture of refined petroleum products (partly)
Distribution of petroleum products	H492 Freight rail transport H494 Freight transport by road and removal services H495 Transport via pipeline H502 Sea and coastal freight water transport H504 Inland freight water transport H512 Freight air transport and space transport H52 Warehousing and support activities for transportation
Retail and petrol stations	G 47.3 Retail sale of automotive fuel in specialised stores
Maintenance and repair of vehicles	G 45.2 Maintenance and repair of motor vehicles
Foundries	C24.5 Casting of metals
Laboratories	M71.2.0 Technical testing and analysis
Other industries	N 81.2 Cleaning activities C 20.3 Manufacture of paints, varnishes and similar coatings, printing ink and mastics

Estimates have been made of the number of companies operating with benzene across the EU28 Member States. The Member States with several relevant companies are (in alphabetical order) Germany, Italy, France, Poland and Spain. For many of the affected sectors, the companies are distributed across all Member States.

The distribution of companies/sites across all the sectors and Member States are displayed below. For the two sectors "Maintenance and repair of vehicles and "Distribution" the split by Member State is based on population shares.

Table 70: Share of companies by Member State in each sector/indusry

	Upstream petroleum	Downstream petroleum	Coking plants	Petrochemical industry	Retail and gas stations	Foundries	Remaining two sectors*
Austria	0.0%	1.3%	4.0%	0.0%	0.0%	0.9%	1.7%
Belgium	0.0%	3.9%	3.0%	4.4%	0.1%	1.6%	2.2%
Bulgaria	0.0%	1.3%	0.0%	0.0%	7.3%	1.8%	1.4%
Cyprus	0.0%	0.0%	0.0%	0.0%	0.6%	0.0%	0.2%
Croatia	0.0%	1.3%	0.0%	0.0%	0.0%	1.2%	0.8%
The Czech Republic	0.0%	2.6%	6.0%	0.0%	0.0%	12.9%	2.1%
Denmark	18.0%	2.6%	0.0%	0.0%	0.1%	0.8%	1.1%
Estonia	0.0%	0.0%	0.0%	0.0%	0.4%	0.2%	0.3%
Finland	0.0%	2.6%	2.0%	1.7%	1.5%	0.7%	1.1%
France	0.0%	9.1%	8.0%	10.2%	15.1%	5.7%	13.1%
Germany	2.1%	14.3%	24.0%	29.6%	0.0%	13.6%	16.2%
Greece	0.5%	5.2%	0.0%	0.0%	17.0%	1.7%	2.1%
Hungary	0.0%	1.3%	2.0%	0.0%	0.1%	2.7%	1.9%
Ireland	0.0%	1.3%	0.0%	0.0%	4.6%	1.0%	0.9%
Italy	0.6%	11.7%	5.0%	6.8%	0.0%	18.7%	11.8%
Latvia	0.0%	0.0%	0.0%	0.0%	1.3%	0.1%	0.4%
Lithuania	0.0%	1.3%	0.0%	0.0%	0.2%	0.2%	0.5%
Luxembourg	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%
Malta	0.0%	0.0%	0.0%	0.0%	0.2%	0.0%	0.1%
Netherlands	1.4%	7.8%	6.0%	27.7%	0.0%	1.9%	3.4%

	Upstream petroleum	Downstream petroleum	Coking plants	Petrochemical industry	Retail and gas stations	Foundries	Remaining two sectors*
Poland	0.5%	2.6%	25.0%	0.0%	0.2%	8.4%	7.4%
Portugal	0.0%	2.6%	0.0%	0.6%	8.3%	2.4%	2.0%
Romania	1.4%	2.6%	0.0%	0.0%	5.9%	2.8%	3.8%
Slovakia	0.0%	1.3%	4.0%	0.0%	0.3%	1.0%	1.1%
Slovenia	0.0%	0.0%	0.0%	0.0%	0.5%	1.3%	0.4%
Spain	0.5%	11.7%	4.0%	7.2%	30.5%	8.8%	9.1%
Sweden	0.0%	3.9%	3.0%	0.0%	0.2%	2.0%	2.0%
United Kingdom	75.0%	7.8%	4.0%	11.7%	5.6%	7.5%	12.9%

* Maintenance and repair of vehicles and distribution

3.2. Exposed workforce

3.2.1. Published sources

<u>EU CAREX data</u>

The CAREX (CARcinogen EXposure) data for Europe show an exposed workforce of about 1.4 million workers distributed on 43 different industries[131]. The table below shows the number of workers exposed to benzene in 1991-1993 (EU15), supplemented with data from 1997 for four additional MS (Estonia, Czech Republic, Latvia and Lithuania).

The industries with the largest number of exposed workers are personal and household services, wholesale and retail trade and restaurants and hotels, land transport, manufacture of plastic products not elsewhere classified and iron and steel basic industries.

Notably, the CAREX data does not include any category for automotive repair and maintenance, the main category in the Canada CAREX database as shown below.

Table 71 - CAREX EU estimate on workers exposed to benzene 1993/1997 (for countries where data from 1993 were unavailable data from 1997 were used instead)

Industry	No. of workers

[131] CAREX EU, available at https://www.ttl.fi/wp-content/uploads/2018/01/EU_5_exposures_by_agent_and_industry.pdf

Industry	No. of workers
Personal and household services	942,495
Wholesale and retail trade and restaurants and hotels	248,303
Land transport	42,848
Manufacture of plastic products not elsewhere classified	16,987
Iron and steel basic industries	14,934
Manufacture of other chemical products	12,721
Manufacture of industrial chemicals	12,498
Manufacture of machinery except electrical	9,600
Construction	8,300
Education services	7,387
Manufacture of fabricated metal products, except	6,800
Petroleum refineries	6,783
Financing, insurance, real estate and business services	5,250
Agriculture and hunting	4,980
Sanitary and similar services	4,613
Water transport	3,001
Research and scientific institutes	2,752
Printing, publishing and allied industries	2,390
Crude Petroleum and Natural Gas Production	1,636
Medical, dental, other health and veterinary services	1,620
Manufacture of furniture and fixtures	1,602
Manufacture of wood and wood and cork products	1,257
Manufacture of electrical machinery, apparatus, appliance	1,091
Electricity, gas and steam	1,060
Services allied to transport	1,013
Manufacture of transport equipment	1,000
Manufacture of textiles	881
Manufacture of miscellaneous products of petroleum	682
Other manufacturing industries	489
Manufacture of footwear	400

Industry	No. of workers
Air transport	293
Food manufacturing	288
Manufacture of paper and paper products	284
Manufacture of wearing apparel, except footwear	250
Manufacture of rubber products	250
Water works and supply	200
Manufacture of other non-metallic mineral products	198
Manufacture of leather and products of leather	189
Non-ferrous metal basic industries	162
Recreational and cultural services	120
Manufacture of instruments, photographic and optical	87
Tobacco manufacture	53
Beverage industries	6
TOTAL NUMBER OF WORKERS	1,367,753
NUMBER OF INDUSTRIES	43

CAREX Canada data

CAREX Canada[132] estimates the number of exposed workers in Canada at 375,000 making up 2% of the Canadian population. Based on a population of 513 million people in the EU, the corresponding figure of exposed workers in the EU would be 10 million if a similar per-capita ratio is assumed. Of these, 88% of the exposed are men and only 12% are women. The CAREX Canada data lists the five most significant exposure industries as shown below. Public administration is mentioned as a significant industry, because firefighters belong under public administration in Canada and firefighters are exposed to benzene during smoke diving. However, the use of RPE during firefighting operations is mandatory, and exposure data to not indicate that firefighters are a relevant exposure group.

Table 72 - CAREX Canada estimate on workers exposed to benzene

Industry	No. of workers in Canada	% of total exposed workforce
Automotive repair and maintenance	40,000	11%

[132] CAREX Canada, available at https://www.carexcanada.ca/en/benzene/occupational_estimate/

Taxi and limo service	30,000	8%
Printing and related support activities	28,000	7%
Public administration (incl. firefighters)	27,000	7%
Automobile dealers	15,000	4%
Others	235,000	63%
TOTAL NUMBER OF WORKERS	375,000	100%

Finnish ASA register

In the Finnish ASA register[133], the data indicate that about 2,000 workers in Finland are exposed to benzene, the majority are men (95%). The largest exposed occupations are motor vehicle installers and repairers, office cleaning personnel etc. and agricultural and industrial machinery installers and repairers. Based on a population of 5.5 million in Finland and 513 million people in the EU, the corresponding figure of exposed workers would be 190,600 in the EU if the same per-capita ratio was assumed.

Table 73 - Finnish ASA estimate on workers exposed to benzene (ASA, 2014)

Occupation	Men	Women	TOTAL
Motor vehicle installers and repairers	229	9	238
Office cleaning personnel etc.	207	7	214
Agricultural and industrial machinery installers and repairers	183	0	183
Process workers in the plastics industry	153	9	162
Aircraft installers and repairers	141	2	143
Freight forwarders, warehouse workers and others.	107	0	107
Non-commissioned officers	85	0	85
Officers	73	0	73
Laboratory workers	29	30	59
Drivers of trucks and special vehicles	56	0	56
Other professions	672	51	723
TOTAL NUMBER OF WORKERS	1,935	108	2,043
% OF TOTAL NUMBER OF WORKERS	95%	5%	100%

133 ASA (2014), ASA 2014 Syöpäsairauden vaaraa aiheuttaville aineille ja menetelmille ammatissaan altistuneiksi ilmoitetut Suomessa. TYÖTERVEYSLAITOS HELSINKI. Available at : http://www.julkari.fi/handle/10024/131073

Italian occupational exposure estimates

Scarselli et al.[134] evaluated a total of 16,271 benzene exposure measurements from the Italian carcinogen exposure database SIREP from the period 1996-2007. In the database, information about the companies (economic activity sector, geographical location and workforce size), the worker (demographic data and occupational characteristics) and exposure (carcinogenic agent, magnitude, frequency and duration) is recorded.

The overall arithmetic mean of measurements was 0.09 ppm and the geometric mean 0.02 ppm. The number of workers potentially exposed in the selected sectors was 37,137 (table 74), and the most predictive independent variables of the exposure level were measurement year and job category. The sectors with the highest estimated numbers of exposed workers were "Retail sale of automotive fuel" (about 16,000 exposed workers) and "Petroleum refinery" (about 6,500 exposed workers).

The table below lists only the sectors better characterized in the database. Certain sectors were excluded because of the limited information on the size of reported workforce (e.g. "Land transport", "Sewage and refuse disposal" and "Maintenance and repair of motor vehicles").

Table 74 - Estimates on workers exposed to benzene from the Italian exposure database (Scarselli et al., 2011)

Sector of economic activity	No. of companies	% of worker exposed	No. of workers exposed
Extraction of crude petroleum	15	50.52	2,104
Petroleum refinery	23	45.44	6,452
Manufacture of other organic basic chemicals	12	38.48	4,321
Manufacture of basic pharmaceutical products	10	3.36	509
Manufacture of pharmaceutical preparations	13	3.53	1,870
Retail sale of automotive fuel	1,009	73.22	16,041
Wholesale of petroleum products and lubricants	15	50.20	5,840
TOTAL NUMBER OF WORKERS			37,137

French SUMER database

[134] Scarselli, A., Binazzi, A., Di Marzio, D. (2011). Occupational exposure levels to benzene in Italy: findings from a national database. Int Arch Occup Environ Health 84(6):617-625.

Data are also reported by the The Medical Monitoring Survey of Professional Risks (Surveillance médicale des expositions aux risques professionnels, SUMER), and which are summarised for the most recent survey concerning below[135]. These data are extrapolations from a sample of workers who self-declare exposure in a survey administered by company medical officers during the workers' regular compulsory medical examination.

The database includes exposure to benzene (excl. benzene in fuels) and exposure to petrol (excl. specific information on benzene).

Table 75 - Workers exposed to benzene (excl. fuels) and petrol in the SUMER survey 2010

Group	Total no.	% of workforce	Duration of exposure within the last week	Extent of exposure
Benzene (excl. benzene in fuels)				
Total	36,900 *	0.2	Without indication: 5,900 Less than 2 h.: 19,200 2-10 h: 7,300 10-20 h: NA >20 h: NA	Not declared: 11,400 Very low: 16,300 Low: 8,600 High: NA Very High: NA
Chemical industry	*3,300*	*1.8*		
Repair of automobiles and motorcycles	*6,900*	*0.2*		
Public administration	*2,600*	*0.1*		
Petrol				
Total	458,100 *	2.1	Without indication: 15,000 Less than 2 h.: 308,000 2-10 h: 100,000 10-20 h: 14,600 >20 h: 20,200	Not declared: 90,800 Very low: 209,600 Low: 132,600 High: 24,800 Very High: 0
Repair of automobiles and motorcycles	164,200	5.2		
Agriculture	12,400	5.1		
Construction	66,800	4.4		
Teaching	8,900	3.1		
Transportation and storage	35,200	2.6		
Administrative and service activities	35,100	2.5		

Note: Low exposure: less than 50% of OEL, High exposure: >50% of OEL, Very high exposure: may exceed OEL. The current French OEL for benzene is 3,250 µg/m3 (1 ppm).
* The sector specific data are only provided for main sectors.

[135] Vinck, L., Memmi, S. (2015) Les expositions aux risques professionnels Les produits chimiques Enquête SUMER 2010. Available at : https://dares.travail-emploi.gouv.fr/dares-etudes-et-statistiques/enquetes-de-a-a-z/article/surveillance-medicale-des-expositions-aux-risques-professionnels-sumer-edition

3.2.2. *Sectoral break-down*

Exposed workforce in the upstream petroleum industry

According to stakeholder consultation, significant exposures are more likely to occur in natural gas production than in crude oil production, as natural gas condensate contains larger concentrations of benzene than crude oil. Occupational exposure settings, however, are similar in both productions, as well as activities leading to exposures (tank work, maintenance during turnaround) are comparable with exposure in the downstream petroleum sector.

No data on the number of workers exposed in the upstream sector or the percentage of the workforce exposed at relevant levels been obtained from the stakeholder consultation.

For the downstream sector, it is estimated that 36% of workers employed (based in workforce data provided by Eurostat) are exposed at the levels provided in the section on exposure levels. In the absence of specific data for the upstream sector it is estimated that the same fraction of the workers in the upstream sector undertake are involved in activities with high benzene exposure such as tank work and maintenance during turnaround.

Estimates on total number of workers and number of workers exposed are compiled in the below table.

Table 76 - Data available for estimating exposed workforce in the upstream sector

Number	Description	Comment	Source of number
1,636	No. of exposed workers in crude petroleum and natural gas production in EU		EU CAREX data (1993/1997)
2,104	No. of exposed workers in extraction of crude petroleum and natural gas in Italy; service activities incidental to oil and gas extraction, excluding surveying	According to reports in the SIREP database, half of the total of workers in the sector is exposed to benzene. The production of crude oil in Italy is very small.	Scarselli et al., 2011
17,694	No. of exposed workers in extraction of crude petroleum and natural gas, service activities incidental to oil and gas extraction extrapolated from Italian figure to the EU.	The estimate is smaller than the other estimate developed for the whole of the EU, corresponding to that the production of crude oil in Italy is small.	Scarselli et al., 2011 and own extrapolation based on population
65,834	Total number of employees in category B06: crude petroleum (40,284) and natural gas extraction (25,551)	Only a fraction of the total number of employees will be exposed	Eurostat, 2016
24,000	Eurostat estimate multiplied with the fraction of exposed derived from the downstream sector (36%)	Justification: Comparable exposure situations in the downstream and upstream sector	Eurostat, 2016; stakeholder consultation

Exposed workforce in the downstream petroleum industry

By the end of 2017, there were about 39 benzene-producing steam cracker plants (owned by 16 companies) and 77 refineries in the EU. The steam crackers and the refineries (including aromatics extraction units/plants) are the main benzene (and other aromatics) producers (90-95% of the production)[136]. All of these companies are large companies with more than 250 employees.

According to Eurostat, there are 1,019 enterprises within the NACE category "C192 - Manufacture of refined petroleum products". Apparently, handling of benzene-containing streams and thus exposure to benzene occurs only in a small fraction of companies producing refined petroleum products.

Estimates on total number of workers and number of workers exposed are compiled in the below table.

Comparing the figures from Eurostat (total number of workers) and the Triskelion study (number of exposed) results in 36% of workers employed within the sector may be occupationally exposed to benzene in some degree. This appears to be a reasonable percentage on the basis of stakeholder consultation responses own observations by companies visited. The estimate of 45,086 is taken on for further consideration in the cost benefit assessment.

Table 77 - Data available for estimating exposed workforce in the downstream sector

Number	Description	Comment	Source of number
6,783	Petroleum refineries	Number of exposed to benzene	EU CAREX data (1993/1997)
123,850	C192 - Manufacture of refined petroleum products	Total number of employees in the sector, from 1,019 enterprises	Eurostat, 2016
45,086	Estimated for workers exposed in manufacture of benzene and benzene containing streams (refineries and steam crackers).	Sum of - direct exposed workers and indirectly exposed workers - estimate is extrapolated from questionnaire responses to the whole of the EU	Triskelion study

Exposed workforce in the coking plants

According to estimates obtained during stakeholder consultation there are 50 coking plants in Europe. Coking plants are usually medium or large companies with around 250 workers of which half are exposed to benzene containing emissions. Comparable with the petroleum sectors, externals may be hired for certain maintenance works. Estimates on total number of workers and number of workers exposed at compiled in the below table.

The estimates deviate by a factor of 2. The estimate based on the number of plants obtained during stakeholder consultation appears more robust as it is derived from information received during a site visit and direct consultation with industry experts and fewer assumptions than the latter estimate. The first estimate is therefore used in the benefits assessment.

[136] FuelsEurope (2018). Statistical report 2018. https://www.fuelseurope.eu/wp-content/uploads/FuelsEurope-Statistical-Report-2018.pdf

Table 78 - Data available for estimating exposed workforce in the coking plants

Number	Description	Comment	Source of number
6,250	Number of exposed workers in coking plants	Based on number of coking plants in EU (50), average no. of employees of 250 per plant (including externals), and a fraction of 50% of exposed	Stakeholder consultation
3,142	Number of exposed workers in coking plants	Based on European production of coking plants, and average production and fraction exposed per coking plant	Eurostat*; Stakeholder consultation

* https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Coal_production_and_consumption_statistics #Supply_of_coke_oven_coke_and_deliveries_to_the_iron_and_steel_industry

<u>Exposed workforce in the petrochemical industry</u>

Around 50 chemical plants in Europe are converting benzene into various derivatives[137].

The Triskelion study estimate an average number of exposed ca. 190 FTEs per site. According to stakeholder consultation, there are between 30 and 50 sites in EU.

The estimate on FTEs exposed provided in the Triskelion study is rather low compared to the CAREX estimate on no. of exposed workers but considered to be more precise and better reflect the current situation. The content of benzene in mixtures has since the mid-1990s, where the CAREX study was undertaken, been restricted and this has likely resulted in lowering the number of workers exposed in the manufacture of some types of chemicals. The Triskelion study estimate is therefore taken forward in the assessment.

Table 79 - Data available for estimating exposed workforce in the chemical industry sector

Number	Description	Comment	Source of number
186,493	C2014 - Manufacture of other organic basic chemicals	Total no. of employed, all enterprises within category	Eurostat, 2016
4,596	C2014 - Manufacture of other organic basic chemicals	Total no. of employed, 50 enterprises within category (accounting for 2.5%) of total no. of employed	Eurostat, 2016; Personal communication with Petrochemicals Europe, 2018
12,498	Manufacture of industrial chemicals	No. of exposed	EU CAREX data (1993/1997)
7,592 (5,694 - 9,490)	Use of benzene as intermediate	Numbers from all responses on workers directly and indirectly exposed extrapolated to the EU. Average of 190 FTEs per site, 30-50 sites in EU.	Triskelion study; Petrochemicals Europe, 2018

[137] See footnote 18

Exposed workforce in distribution

According to stakeholder consultation, there are usually between 40 and 100 people employed at a bulk tank storage site with 10 – 30% of the workers exposed related to filling and loading activities. Estimates on total number of workers and number of workers exposed at compiled in the below table. The estimate of 75,230 workers in the EU, extrapolated from information for five MS provided by Petrochemicals Europe[138], has been used for the further calculations.

Table 80 - Data available for estimating exposed workforce in the distribution of benzene and benzene-containing streams

Number	Description	Comment	Source of number
9,792	No. of exposed workers at tank farms	Sum of directly exposed workers and indirectly exposed. Numbers from all responses (n=64) of the industry SEA survey, no extrapolation to the EU was done.	Triskelion study
1,250	No. of exposed workers at tank farms	Estimate for DE, FR, BE, NL, LU. Not extrapolated to EU.	Personal communication with Petrochemicals Europe, 2018
3,582	No. of exposed workers at tank farms in EU	Estimate for DE, FR, BE, NL, LU extrapolated to the EU based on population	Personal communication with Petrochemicals Europe, 2018
25,000	No. of exposed tank drivers	Estimate for DE, FR, BE, NL, LU. Not extrapolated to EU.	Personal communication with Petrochemicals Europe, 2018
71,648	No. of exposed tank drivers in EU	Estimate for DE, FR, BE, NL, LU extrapolated to the EU based on population	Personal communication with Petrochemicals Europe, 2018
26,250	No. of exposed workers at tank farms and tank drivers	Estimate for DE, FR, BE, NL, LU. Not extrapolated to EU.	Personal communication with Petrochemicals Europe, 2018
75,230	No. of exposed workers at tank farms and tank drivers in EU	Estimate for DE, FR, BE, NL, LU extrapolated to the EU based on population	Personal communication with Petrochemicals Europe, 2018

Exposed workforce in the retail and petrol stations

By the end of 2017, there were 74,340 petrol stations in the EU MS[139]. Estimates on total number of workers and number of workers exposed at compiled in the below table.

Scarselli et al. (2011)[140] estimate that 16,041 workers in "retail sale of automobile fuel" may be exposed to benzene representing 73% of the workers in the stations in Italy. Extrapolated to the entire EU on a per capita basis, the total would correspond to approximately 140,000.

[138] See footnote 18
[139] See footnote 18
[140] See footnote 134

In the majority of the MS, today filling assistants are not used. According to Concawe, filling assistants are used in 5% of the petrol stations across the EU. It is for the calculations assumed that 5% of the total staff reported for NACE code G473, “Retail sale of automotive fuel in specialised stores” may be filling assistants, resulting in 21,600 exposed workers. This estimate is taken on in the assessment.

Table 81 - Data available for estimating exposed workforce in the fuel retail and petrol stations

Number	Description	Comment	Source of number
430,000	G473 - Retail sale of automotive fuel in specialised stores	Total no. of employed, all enterprises within category	Eurostat, 2016
140,000	Exposed workers at petrol stations	Based on numbers of workers exposed in Italy, extrapolated to the EU on per capita basis	Scarselli et al., 2011
21,600	Exposed workers at gas stations (attendants and pump calibration)	No. of exposed workers comprising 5% of total employees and an additional number of pump maintenance workers (1 worker per 1000 pumps)	Eurostat, 2016, Stakeholder consultation

Exposed workforce in maintenance and repair of motor vehicles

Estimates on total number of workers and number of workers exposed at compiled in the below table. The Finnish ASA database indicates 248 exposed in Finland whereas the Finnish register of biological monitoring indicates that “Car maintenance and repair work employs about 8,000 people, some of whom may be exposed to benzene”[141].

For the sector “Repair of automobiles and motorcycles”, the French SUMER Database estimates that 6,900 workers are exposed to benzene (excl. benzene in petrol) while 164,200 workers are exposed to petrol.

Eurostat lists a total of 1.57 million workers employed within "Maintenance and repair of motor vehicles". It will for the further estimations be assumed that half of the workers in the sector are exposed at the levels reported under exposure concentrations corresponding to 785,000 workers. The percentage is based on the authors’ own observations in Denmark. The challenge in estimating the number of exposed workers from Eurostat data on total workforce within a sector is to define the number of workers involved in those exposure groups represented by the available exposure data. Data extrapolated on a per capita bases from data for Canada and France would result in about 50% higher numbers, whereas data extrapolated from Finnish data result in much lower numbers.

[141] Kiilunen, M. (2012): Biological monitoring – annual statistics 2012, Finnish Institute of Occupational Health. https://www.julkari.fi/bitstream/handle/10024/135070/Biological%20monitoring.pdf?sequence=1

Table 82 - Data available for estimating exposed workforce in the maintenance and repair of motor vehicles

Number	Description	Comment	Source of number
1,569,416	G452 - Maintenance and repair of motor vehicles	Total no. of employed, all enterprises within category	Eurostat, 2016
784,708	Exposed workers in maintenance and repair of motor vehicles	Based on Eurostat data assuming 50% of the people employed exposed	Eurostat, 2016; own estimate
238	Exposed in Finland, 2014	EU28 (per capita estimate): 21,983	ASA database
40,000	Automotive repair and maintenance, number of exposed workers in Canada	EU28 (per capita estimate): 1,094,400	CAREX Canada
164,200	Exposed to petrol in France	EU28 (per capita estimate): 1,254,000	SUMER database

Exposed workforce in the foundries

Estimates on total number of workers and number of workers exposed have been received from the European foundry association (CAEF), see below table. According to CAEF, about one third of all workers within the foundry sector are potentially exposed.

The EU CAREX does not specifically include foundries but indicates 14,934 exposed persons in “Iron and steel basic industries”.

Table 83 - Data available for estimating exposed workforce in the foundries

Number	Description	Comment	Source of number
154,600	Employed workers in foundries	Total no. of employed	Stakeholder consultation
49,000	Potentially exposed workers in foundries	No. of exposed	Stakeholder consultation
202,924	Employed workers in foundries	Total no. of employed in Casting of metals (code 24.5)	Eurostat, 2016
68,000	Potentially exposed workers in foundries	No. of exposed	Eurostat, 2016; Stakeholder consultation

Exposed workforce in laboratories

Exposures in production laboratories are generally low, whereas in R&D facilities occasionally more elevated exposures occur during petrol handling, an activity which may, however, be infrequent.

Among laboratory workers only those employed in R&D facilities and engaged in test fuel blending may have occasional elevated exposure to petrol vapour.

As described in the next section, the EU CAREX indicates that 2,752 workers in R&D institutions may be exposed to benzene. The Finnish ASA database indicates 59 laboratory workers may potentially be exposed to benzene in Finland in 2014 (extrapolated to the EU it may approximately be 6,000). As the available exposure data represents only laboratories technicians involved in the processes described above, the actual number of technicians exposed at elevated levels in estimated to be significantly lower than the total number of potentially exposed technicians.

Table 84 - Data available for estimating exposed workforce in the R&D petrochemical laboratories

Number	Description	Comment	Source of number
2,752	Exposed workers in R&D institutions	Comprising R&D personnel from all sectors	EU CAREX data (1993/1997)
6,000	Laboratory workers	Extrapolated to the EU from Finnish ASA estimate	ASA, 2014
500	Exposed workers in R&D laboratories in the petroleum sector		Own estimate

<u>Exposed workforce in other occupations</u>

A large number of workers may potentially be exposed at low levels in a number of occupations which may be divided on:

- Exposure to low levels of benzene in paints, adhesives, sealants, printing inks.
- Exposure to benzene in ambient air in city areas with high traffic, or exposure to benzene generated by fires.

Very limited data are available on 8h TWA for these occupations. Available data for short term exposure shows that exposure levels may be well above a threshold level of 0.05 ppm, but the data indicates that likely a very small part of the workers may be regularly exposed at 8h TWA levels above the 0.05 ppm. It is considered that the exposure levels are very low as compared to the levels e.g. in the petrochemical sector and the actual number of workers exposed at a level above the threshold has not been quantified because the contribution from this group to the total benefits and costs is estimated be very low as compared to the effects on other sectors. As the threshold for health effects is 0.05 ppm, this group of workers, even the number is large, will not contribute significantly to the total body burden.

The number of workers potentially exposed at low levels below the assessment levels of this study is considered to be very high as a high number of workers on a regular basis or from time to time use mixtures with low levels of benzene. The EU CAREX data indicates that about 940,000 workers within personal and household services may be exposed to benzene. The high number from this occupation is not confirmed by other surveys, but the Finnish ASA register indicates that 214 office cleaning personnel, etc. may be exposed to benzene (more than 20,000 if extrapolated to the entire EU). Besides, the CAREX database include a number of occupations where the exposure to benzene is due to low levels in applied mixtures such as construction, manufacture of furniture, manufacture of textiles, manufacture of wood products, etc.

The CAREX Canada indicates a large number of exposed workers in Canada within the occupations taxi and limo service (may be both benzene in petrol and ambient city air), printing and related support activities and public administrations (e.g. firefighters). The available data do not allow for a very certain estimate of the total number of workers potentially exposed at levels below the assessment levels, but it may likely be in the 200,000 - 2,000,000 range. Workers within many of these occupations may have been exposed to significantly higher levels before the restrictions of benzene in products went into force, and may have contributed significantly to the total occupational health effects of benzene.

3.2.3. Summary on workers exposed

The data collected through consultation for this study provides evidence of around 1 million workers are currently exposed to benzene. The table below gives an overview of the exposure concentrations and number of exposed workers taken forward for the model calculations.

The exposure data presented in the below table is compiled on data from both published sources and stakeholder consultation. Mean and median concentrations were calculated by taking simple (arithmetic) means of available mean and median data. 95th percentiles were calculated based on average relationships between mean and 95th percentiles from datasets were both mean and 95th percentiles were available. All exposure values were given the same weight irrespective of number of samples, as the number of samples is not representative for the occurrence of certain exposures. This approach may contribute to a conservative estimation of exposure concentrations, as there is a tendency that measurements are more often taken in high exposure situations compared to low exposure situations.

Short-term measured data, e.g. 10 min measurements during loading of a truck, have been omitted. The below exposure concentration estimates are therefore mostly based on longer term measurements (e.g. 60 – 380 min) or full shifts, thus being representatives for 8-h TWA. In a few cases, sampling duration is not known. In case that such values are actually only descriptive for short-term exposure, they will contribute to a conservative estimation of exposure concentrations values used as input data for the model calculations.

It is assumed that the exposed workers are lognormal-distributed over the range of exposure concentrations, and the below data have been used to fit a lognormal distribution for each sector.

Apart from the sectors listed in the table below, it cannot be excluded that exposures exceeding the OEL of 0.05 ppm proposed by RAC may also occur in other sectors, for examples in manufacture of glues and adhesives, car painting or shoe manufacturing. Presently available data indicate that elevated exposures mostly occur as short-term exposures, and that the number of workers subject to elevated long-term exposures not relevant. Sectors, where exposure may occur due to use of benzene-containing products (e.g. paints, inks, adhesives, mineral spirits) are therefore not included in the further calculations.

Table 85 - Exposure data used for the calculation of cases

Sector	Exposure concentration (µg/m³) representative for 8-h TWA*			No. of exposed workers
	Mean **	Median	95th percentile	
Upstream petroleum industry	1,040	65	3,250****	24,000
Downstream petroleum industry	510	221	1,463	45,000
Coking plants	1,030	150	3,250****	6,250
Petrochemical industry	420	65	1,300	7,592
Distribution	680	250	1,944	75,200
Retail and petrol stations	180	40	500	21,600
Maintenance and repair of motor vehicles	170	55	450	785,000
Foundries	1,220	500	3,250***	49,000
Laboratories	250	80	726	500
TOTAL				**1,012,500**

* Aggregated concentrations data based on published data (see section 4.4.1) and data obtained during stakeholder consultation (not presented here).
** Calculated from the log-normal distributions fitted on the basis of the median and 95th percentile.
*** The 90th percentile is 3,160 and the 95th is set at the existing OELV of 3,250 µg/m³.
**** Available data indicated a higher 95th percentile than the existing OELV of 3,250 µg/m³. For the estimations it is assumed that the companies are in compliance with the existing OELV and the 95th is set at the existing OELV.

Annex 7: Route(s) of exposure, adverse health effects

Acrylonitrile

Routes of exposure and uptake[142]

The primary route of exposure to acrylonitrile for the worker population is through inhalation, although exposure can also occur through dermal contact[143]. Indeed, SCOEL[144] note that the high potential for acrylonitrile to penetrate skin can lead to a high risk of accidents. Strict controls for the handling of the compound in the workplace are therefore required. The effects following exposure to acrylonitrile may be local at site of contact or systemic following exposure via inhalation or dermal routes.

Adverse health effects

Acrylonitrile has a harmonised classification as carcinogenic (Carc 1B[145]) under the Classification, Labelling and Packaging (CLP) regulation[146]. According to the International Agency for Reasearch on Cancer[147], there is "*inadequate evidence in humans for the carcinogenicity of acrylonitrile. There is sufficient evidence in experimental animals for the carcinogenicity of acrylonitrile*"[148]. In consequence, acrylonitrile is classified as possibly carcinogenic to humans (Group 2B[149]) by IARC.

Primary target for acrylonitrile toxicity is the central nervous system. The main concern is carcinogenicity in the brain, but acrylonitrile is also acutely neurotoxic. In animal studies, acrylonitrile was found to be a multiple-site carcinogen. Acrylonitrile also causes local irritation of the skin, eyes and respiratory tract as well as skin sensitization[150].

Nickel compounds

Routes of exposure and uptake

The primary route of exposure for the worker population is by dermal contact or by inhalation of aerosols, dusts, fumes, or mists containing nickel. Dermal contact may also occur with nickel solutions, such as those used in electroplating, nickel salts, and nickel metal or alloys. Nickel-

[142] ECHA (2018), Background document in support of the Committee for Risk Assessment (RAC) evaluation of limit values for acrylonitrile in the workplace. ECHA/RAC/O-0000001412-86-187/F. Available at: https://echa.europa.eu/documents/10162/13641/acrylonitrile_bg_annex1_en.pdf/600bc12b-f2b4-16f6-0164-25153b48743d

[143] Scelo (2004) *et al.*, *"Occupational exposure to vinyl chloride, acrylonitrile and styrene and lung cancer risk (Europe)"*.

[144] SCOEL (2003), *"Recommendation from Scientific Committee on Occupational Exposure Limits for Acrylonitrile"*. SCOEL/SUM/104, December 2003.

[145] A category 1B (Carc1B) is a substance which is presumed to have carcinogenic potential for humans

[146] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272

[147] The International Agency for Research on Cancer (IARC) is part of the World Health Organization. IARC coordinates and conducts both epidemiological and laboratory research into the causes of human cancer.

[148] IARC (1999), "*Monographs on the evaluation of carcinogenic risks to humans: re-evaluation of some organic chemicals, hydrazine and hydrogen peroxide (Part 1-3, Volumn 71)*". Available at: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono71.pdf

[149] Possibly carcinogenic to humans

[150] See footnote 142

containing dust may be ingested where poor work practices exist or where poor personal hygiene is practiced[151].

Adverse health effects

According to IARC, there is "*sufficient evidence in humans for the carcinogenicity of mixtures that include nickel compounds and nickel metal. These agents cause cancers of the lung and of the nasal cavity and paranasal sinuses*" and "*in view of the overall findings in animals, there is sufficient evidence in experimental animals for the carcinogenicity of nickel compounds and nickel metal. Nickel compounds are carcinogenic to humans (Group 1*[152]*)"*[153].

The primary target for nickel toxicity after inhalative exposure is the respiratory tract, especially the lung. Epidemiological studies associate occupational exposure to nickel with an increased risk to develop lung cancer, fibrosis and to a lesser extent nasal cancer. In experimental animals chronic inflammation of the lung and fibrosis were also observed. Nickel is also a skin sensitizer and, although uncommon, a respiratory sensitizer. In animal studies, nickel also had adverse reproductive effects on both fertility and development[154].

Benzene

Routes of exposure and uptake[155]

Benzene is readily absorbed by all routes (inhalation, dermal and oral), of which inhalation is the most important route of occupational exposure. Mean inhalation absorption has been reported in humans ranging from approximately 50 to 80%[156].

Dermal absorption of benzene vapour is possible. However, the uptake is small compared to the uptake via inhalation[157].

Liquid benzene can be absorbed through human skin, although this is not as substantial as absorption following inhalation or oral exposure. Under normal condition the contribution of dermal uptake to total uptake might be low as evaporation from the skin surface will decrease the dermally absorbed amount. However, the dermal route can be an important contributor to total benzene exposure in certain situations, such as immersion of the skin in solution or when the airborne concentration of benzene is very low[158].

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[151] See footnote 116

[152] IARC classification: carcinogenic to humans

[153] IARC (1999), "*Nickel and nickel compounds (updated 26 July 2017) monographs on the evaluation of carcinogenic risks of chemicals to humans (Volumn 100c)*". Available at: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono100C-10.pdf

[154] See footnote 18

[155] See footnote 22

[156] Dutch Expert Committee on Occupational Safety of the Health Council of the Netherlands (2014), "*Benzene, Health-based recommended occupational exposure limit*". No. 2014/3. Available at: https://www.gezondheidsraad.nl/en/task-and-procedure/areas-of-activity/healthyworking-conditions/benzene-health-based-recommended

[157] RAUMA *et al.* (2013), "*Predicting the absorption of chemical vapours*". Advanced Drug Delivery Reviews 65:306-14.

[158] WILLIAMS *et al.* (2011), "*Dermal absorption of benzene in occupational settings: estimating flux and applications for risk assessment*". Crit Rev Toxicol 41(2): 111-142.

For solvents used for cleaning that contained benzene at concentrations of less than 0.1%, the amount of benzene absorbed through the skin over a long period was significant, depending on exposure time and exposed skin surface areas[159].

Adverse health effects

Benzene has a harmonised classification under the CLP Regulation[160]. Benzene is classified for carcinogenicity (Carc 1A[161]) and mutagenicity (Muta 1B[162]). In the recently published IARC monograph[163] benzene was classified as carcinogenic to humans (Group 1[164]). In this report new studies published since the last assessment in 2012 were considered. However, the conclusion was not changed.

Major target organs for non-cancer effects of benzene are[165]:

- The bone marrow and
- the haematological system

Genotoxicity (chromosomal damage) in the haematological system is likely to precede haematotoxicity and carcinogenicity. After repeated exposure, benzene can damage the haematopoietic system (e.g. changes in the bone marrow, leukocytopenia, thrombocytopenia, aplastic anaemia with pancytopenia). It has also been shown that benzene has toxic effects on the immune system by suppression of humoral and cellular immune responses. This is a consequence of the toxic effects of benzene on haematopoiesis in the bone marrow. At high concentrations, benzene causes depressant effects on the central nervous system. If swallowed, pulmonary oedema and haemorrhage can be caused by aspiration[166].

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[159] KALNAS and TEITELBAUM (2013), "*Dermal absorption of benzene: implications for work practices and regulations*". Int J Occup Environ Health 6: 114-121

[160] See footnote 146

[161] A category 1A (Carc1A) carcinogen is a substance known to have carcinogenic potential for humans

[162] A category 1B mutagen (Muta1B) is a substance known to induce heritable genetic mutations or to be regarded as if they induce heritable mutations in the germ cells of humans.

[163] IARC (2018), "*Benzene. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (Volume 120)*".

[164] Carcinogenic to humans

[165] See footnote 18

[166] See footnote 18

Annex 8 – Process for setting binding OELs and associated provisions under the CMD

Step 1: Social partners consultation

TFEU Article 154 requires a formal two-stage consultation of the social partners at EU level (management and labour) prior to submitting proposals in the social policy field. As regards the present initiative this consultation took place in 2017 and addressed the third and fourth amendments of the Annex III of the CMD. annex 2 provides further information on the outcomes of the consultation.

Step 2: Priority setting

It is not realistic to set an OEL for every hazardous chemical that may be used at the workplace. Instead it is appropriate to identify and target priority substances.

The selection of the carcinogens considered in this Impact Assessment was based on a consultative approach including stakeholder engagement at member states and social partner levels, and taking into account general considerations such as the following:

- Potential to cause adverse health effects resulting from occupational exposure.
- Processes resulting in exposure or combined exposures to chemicals with the potential to cause adverse health effects resulting from a work activity for which markers of exposure are needed.
- Emerging specific issues on a basis of reported evidence and expert judgment.
- Degree of evidence for adverse effects.
- Characteristics of the adverse effects (severity, potency, reversibility, specificity).
- Estimated number of workers exposed.
- Identified exposure patterns that pose difficulties for the control of exposures.
- Policy considerations, such as problematic disparities with or between other relevant threshold values, degree of stakeholders' interest in having an EU OELV, or other institutional priorities.

Considering the occupational cancer burden, it is important to note that when identifying a priority substance, stakeholders look at the whole range of potential negative health effects (carcinogenic and non-carcinogenic) which could be prevented by establishing an EU level OEL. For example, concerning acrylonitrile, although an impact on cancer prevention is somewhat limited, it will have a substantial impact on prevention of other relevant non-cancer health problems such as nasal irritation (preventing up to 408 cases) which otherwise would cause sufferings to these workers and compromise their quality of life. As acrylonitrile (and the other two substances) falls under CMD, in order to prevent the whole range of health problems, an OEL can only be established under this directive.

The Commission is committed to continuing efforts to strengthen application of such criteria in the future.

Step 3: Scientific evaluation and public consultation

Article 16 of the CMD states that scientific/technical data should be included in the basis on which OELs are set, but CMD does not determine which scientific body should be the source of such data. However, Based on a Service Level Agreement (SLA) signed by DG EMPL and ECHA, theRisk Assessment Committee (RAC) assists the Commission delivering scientific evaluations, upon request, on the toxicological profiles of each of the selected priority chemical substances in relation to their adverse health effects on workers. These scientific evaluations shall, where appropriate, include proposals for Occupational Exposure Limit values (OELs), biological limit values/biological guidance values and/or notations. This task shall be carried out on the basis of the latest available scientific and technical data and take into account the specific context of occupational exposures at the workplace.

Scientific information from other sources can also be taken into account as long as the data is adequately robust and is in the public domain (e.g. IARC monographs or conclusions of national OEL-setting science committees).

RAC carries out scientific evaluation at EU level based on the methodology agreed withing the ECHA/RAC-SCOEL Joint Task Force and as a result publish an Opinion on scientific evaluation of occupational exposure limits for the selected priority chemical substances.

RAC procedure for the adoption of an Opinion includes an external consultation of relevant stakeholders. This ensures scrutiny of the scientifc evidence and methodological approach used by RAC and ensures transparency of the process.

RAC has concluded Opinions on all the carcinogens analysed in section 6 – further details are provided in annex 1.

More information on the ECHA methodology used by RAC can be found on the ECHA website: https://echa.europa.eu/en/about-us/who-we-are/committee-for-risk-assessment

Step 4: Tripartite consultation of Member States and social partners

While the aim of ensuring the protection of the health of workers is maintained, binding OELs set under CMD must also reflect other factors such as 'feasibility' and take into account the views of the social partners. For this reason the Opinion of the ACSH is requested.

The ACSH is a tripartite body set up in 2003 by a Council Decision (2003/C 218/01) to streamline the consultation process in the field of occupational safety and health and rationalise the bodies created in this area by previous Council Decisions. The ACSH remit is to assist the Commission in the preparation, implementation and evaluation of activities in the fields of safety and health at work. The ACSH is composed of three full members per Member State, representing national governments, trade unions and employers' organisations, also organised in three separate interest groups within the Committee.

The ACSH is supported by working parties of experts on given topics of interest according to mandates agreed by the plenary Committee. These working parties are also tripartite but usually with smaller selected expert membership.

The ACSH Working Party on Chemicals (WPC) undertakes broader chemicals policy support for the ACSH and Commission and in particular detailed technical and policy negotiation of EU limit values. This process is informed by all available evidence regarding appropriate and achievable limit values including adopted RAC Opinions and any national OELs

It is during these, often complex, discussions that the level of ambition which is appropriate for a specific EU OEL for a carcinogen is established, taking into account the views of representatives from the government, workers, and employers interest groups.

The ACSH discusses adopted RAC Opinions (and/or other appropriate scientific evidence) and adopts a formal Opinion.

The adopted ACSH Opinions include, where necessary, specific comments from the interest groups (Government, Employers and Workers) which broadly reflect the principal points maintained by each interest group throughout discussions of the Working Party on Chemicals (WPC).

The ACSH has adopted opinions for all priority substances foreseen for the fourth amendment of the CMD[167], proposing one or several binding OELs for each of them accompanied by transition periods, a skin notation for Benzene and Acrylonitrile and a skin and respiratory sensitisation notation for Nickel compounds as possible approaches for these chemicals.

In practice an OEL emerging from this process reflects a deep technical, socioeconomic, and political consideration of what is achievable by employers across the EU and also ensures that workers' health is adequately protected. These Opinions are also adopted taking into account that OELs for carcinogens exist within the broader context of the CMD elimination/minimisation obligation, which establishes an appropriate and exceptionally high legal standard for workplace- and process-specific risk control.

Step 5: Impact assessment

Between 2018 and 2019 an external contractor evaluated, on behalf of the Commission, health, socioeconomic and environmental impacts of the proposed amendments to CMD in order to perform an impact assessment according to the regulatory procedures in place.

The impact assessment takes all of the above steps into consideration and the IA Report is presented to the Commission services Regulatory Scrutiny Board in accordance with the relevant internal rules for initiatives with foreseeable significant impacts.

The options for action proposed by the ACSH are established through a thorough scientific, technical and socioeconomic discussion and in general the tripartite agreements reached in the Advisory Committee would be put forward in the eventual Commission's proposal. However, in line with the Better Regulation guidelines, an IA is conducted before presenting the proposal. In the IA the Commission verifies the ACSH opinions on the basis of a dedicated study.

As a result of the IA the ACSH-based options could be withheld, retained or complemented.

A proposed action is withheld if the ACSH opinion has not been sufficiently consensual, and the Commission's assessment leads to concerns about the proposal (e.g. as regards legality or clarity). This does not mean that the Commission discards the option. Rather, important additional elements are needed before further assessing the option.

[167] The links to these ACSH opinions are available at the Annex II

An option is retained if the ACSH opinion has been clear and consensual, there are no concerns about legality and clarity of the option and the socioeconomic assessment confirms the robustness of ACSH opinions in terms of effectiveness, efficiency and coherence.

An option may be further complemented if the ACSH opinion did not take into account an important scientific element, such as the need to establish a skin notation.

Agreement of the RSB is a prerequisite before presenting the draft proposal for adoption by the college of Commissioners.

After completion of these steps the Commission prepares the legislative proposal which will be adopted following the ordinary legislative procedure. The adopted Directive will be published in the EU Official Journal and Member Stages will then transpose the limit values and any associated notation into their national legislation by the date set in the Directive.

The OELs adopted will then ensure a consistent level of minimum protection for all workers in the EU, while leaving the Member States the option of keeping or setting more favourable standards by introducing more stringent OELs.

Within the CMD there is an obligation for employers to apply the appropiate measures at the workplace to ensure that the exposure of workers to these substances do not exceed the OEL. The monitoring and of application and enforcement will be undertaken by national authorities, in particular the national labour inspectorates.

Annex 9 – Options discarded at an early stage

Several other options have been discarded as they were considered disproportionate or less effective in reaching the objectives of this initiative. These options are related either to the OELs setting, or to the choice of another instrument, or to the support of the SMEs.

Options related to the way of setting OELs

A. Banning the use of the carcinogenic chemical agents

For most carcinogens even a very low OEL does not completely eliminate the risk of triggering a cancer. The risk could only be reduced to zero by eliminating the presence/use of the substance in the workplace.

Indeed, substitution is the first option in the hierarchy of risk management measures under the CMD that an employer needs to consider. This means that if it were technically feasible, employers should already have replaced use of the concerned chemical agents with safer alternatives.

Wherever substitution is a suitable alternative for use of the chemical agents in question the CMD already requires this, regardless of the existence of an OEL. As this legal standard already establishes that these carcinogens should not be used in the workplace where alternatives are available, establishing a more strict prohibition in the form of a ban would constitute a disproportionate measure with a strong negative impact on businesses.

B. Directly adopting the most stringent national OEL

For most of the carcinogens some Member States adopted OELs more stringent than considered in this impact assessment. It could be argued that such OELs could be made binding across the EU based on an assumption that what is achievable in one Member State should be achievable in all.

However, the EU sets minimum standards in this area and OELs need to be seen in the context of the minimisation principle. This means that industries have the obligation to minimise exposure below existing OELs if that is technically feasible.

Options related to the choice of another instrument

C. Providing industry-specific scientific information without amending CMD

Another option could be for the Commission to collect and provide industry-specific scientific information to support employers in complying with the CMD obligations.

Apart from the practical difficulties related to collection of relevant data for the multitude of sectors concerned, it is considered that this option would not be effective in achieving the objectives of the initiative for the following reasons:

- the way the information is used by employers would not be enforceable by surveillance authorities;

- such an option would not fit with the overarching legal framework of the CMD, which provides for general exposure management requirements to be specifically supplemented by EU-wide minimum standard OELs;
- in some cases, extensive industry- and chemical agent- specific information and guidance already exists and should be taken into account by employers during risk assessments – but this has not demonstrably addressed harmful exposures at EU level.

D. Market-based instruments

Market-based instruments such as subsidies, tax breaks or reductions of social insurance contributions, are sometimes used by Member States to incentivise business to comply with health and safety rules. Such instruments can effectively support compliance with exposure limits. However, to be applied effectively in this context, such mechanisms would need to be linked (directly or indirectly) with the actual levels of exposure at firm level. This would require much improved data collection which would likely result in being extremely costly and cumbersome. It should also be noted that these instruments remain in the hands of Member States and the extent to which they are used varies significantly[168]. This option alone would therefore not be effective in ensuring the same level of minimum protection across the EU.

E. Industry self-regulation

Certain industry initiatives like voluntary product stewardship programmes by companies and sectors, or autonomous social partner agreements, are not legally binding and not applied in all sectors or companies concerned.

Such agreements are very useful tools to improve the situation over time, however, due to the fact that their rules and obligations for members are not always implemented and thus enforced by national authorities, these initiatives can only be considered as complementary tools.

F. Regulation under other EU instruments (REACH)

The OSH Directives and REACH are complementary, and clear synergies between REACH and worker protection legislation can be seen – these are set out in more detail in section 4 of this report and in annex 10.

In the case of the present proposal, setting binding OELs under the CMD is the appropriate regulatory instrument. Among the reasons in support of this approach there is the fact that CMD covers worker exposure to carcinogenic agents released by any work activity, whether produced intentionally or not, and whether available on the market or not, such as process generated substances in the workplace.

As mentioned in section 4, industrial processes are not subject to the REACH restriction for benzene. Reviewing the OEL for this substance used in industrial processes is therefore appropriate to improve the protection of workers.

Protection of workers from the exposure to nickel compounds would also be improved by setting an OEL at the EU level. Indeed, the current REACH restriction concerns the use of nickel

[168] EU-OSHA."Economic Impact of Occupational Safety and Health in the Member States of the European Union." Available at https://osha.europa.eu/en/publications/reports/302

and its compounds in jewellery and articles which are intended to come into contact with the skin. In addition, three EU Members States (France, Germany and Hungary) have carried out Regulatory management option analysis (RMOAs) for some nickel compounds. As a result of this RMOA approach, the EU has prioritised setting a binding OEL as the most appropriate risk management measure for nickel compounds.

As the REACH restriction for acrylonitrile does not concern the industrial uses, the setting of an OEL for this substance under the CMD will improve the protection of workers as they are not covered by the REACH restriction.

Furthermore, CMD is intended to set OELs, which are an important part of the wider OSH approach to managing chemical risks[169].

G. Guidance documents

As non-regulatory alternatives, guidance documents or examples of good practice could be developed and disseminated in co-operation with the EU-OSHA and/or the ACSH and its relevant working party. This could also include the development of awareness raising campaigns for employers and workers alike on the prevention of risks arising from workers' exposure to categories 1A and 1B carcinogenic and mutagenic substances. However guidance documents by itself would not be considered effective enough in reaching the objectives of this initiative. They are complementary and provide an added value to setting OELs.

Option related to the support of the SMEs

H. Adapted solutions for SMEs

SMEs should not be generally exempted from the scope of the initiative as their exclusion would mean that a very significant number of European workers would not be covered by health and safety at work legislation, with a clear distortion and inequality in the application of the EU legislative framework and with a risk of compromising the underlying social policy objectives and fundamental rights.

corresponding OEL in the Annex III, thereby pre-empting the preparatory work of the European Commission. Therefore, as DEEE was addressed in the second revision of the CMD, there was no need anymore to consider it in the framework of the fourth revision of the CMD.

[169] For a detailed analysis of the differences between CMD and REACH see section 4.2, page 34, of SWD(2016)152/2.

Annex 10 – Consistency and synergies with the REACH Regulation[170]

The REACH Regulation, adopted in 2006, consolidated and evolved several parts of the EU chemicals legislation, including those relating to risk assessment and to the adoption of the risk management measures. The REACH Regulation established the 'registration' of all chemicals produced or imported above 1 tonne on the EU market and 'authorisation' and 'restriction' as risk management measures to control the exposures of chemicals, including substances of very high concern (SVHC), at the workplace or for industrial uses.

A carcinogenic chemical may appear complementary on both, CMD Annex III and the REACH Regulation Annex XIV (the list of SVHC which can only be placed on the market or used if an authorisation has been granted for a specific use by the European Commission), as well as on the REACH Regulation Annex XVII (restricted substances).

The OSH Framework Directive – under which CMD is operational – applies without prejudice to existing or future national and EU provisions which are more favourable to the safety and protection of the health of workers at work. The REACH Regulation in turn applies without prejudice to worker protection legislation, including the CMD.

Clear synergies between the REACH Regulation and worker protection legislation exist, in particular the REACH Regulation 'registration' should result in more information being available to inform chemicals risks assessment.

The REACH Regulation 'authorisation' and 'restrictions' also establishes, for a given chemical agent, a clear and renewed pressure to substitute it with safer alternatives, and can drive industry to improve the risk management measures and operational conditions at the workplace in order to improve the safety and the protection of workers. At the same time existing OELs and/or the underlying information used for setting the OEL can be used to derive DNELs under the REACH Regulation.[171]

An authorisation under the REACH Regulation may only be granted for specific uses and operators who have demonstrated that the risks are either adequately controlled (the 'adequate control route') or when the socio-economic benefits outweigh the risk arising from the use (the 'socio-economic route') and there are no suitable alternative substances or technologies.

Workers exposure is the main exposure scenario today for almost all substances listed in Annex XIV as most of these chemicals are used in industrial settings. For some substances restrictions in marketing and use are important risk management measures under REACH, to be applied at EU level by all companies.

Applicants for authorisation must include, amongst other elements, for each of the uses covered in their application, an assessment of the exposure of workers to the substance(s) and

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[170] See footnote 9

[171] ECHA 2012 (updated 2016): Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.8. Available at: https://echa.europa.eu/guidance-documents/guidance-oninformation-requirements-and-chemical-safety-assessment

the related risk, at the individual workplaces concerned or over a representative sample of workplaces. If the risk management measures set out in the application are not judged to be appropriate and effective by ECHA's Risk Assessment Committee, conditions and/or monitoring arrangements can be imposed in the authorisation decision to reduce exposure and risks further, including biomonitoring and regular occupational exposure measurements.

However, some uses of substances are not covered by the authorisation requirement, namely intermediates[172] and unintended process generated substances. Intermediates as defined by the REACH Regulation are chemical substances which are manufactured for and consumed in or used for chemical processing in order to be transformed into another substance[173]. Occupational exposure to intermediates may nevertheless occur for example during cleaning, maintenance, etc, where residues may be present and/or where process-streams are interrupted and containment may be compromised.

The co-existence of a CMD OELs alongside the REACH Regulation authorisation will provide several important benefits for the practice of both OSH and the REACH Regulation worker protection provisions:

- CMD applies to all potential worker exposures, including those associated with intermediates, and process-generated substances, or resulting from unintended or misuse-related release.
- For so-called non-threshold carcinogens, the OEL-setting process provides a thorough and robust process for establishing minimum standard exposure levels – ultimately passing through the co-legislator for adoption – based on a science and stakeholder consultation based process. The overall relationship between the REACH Regulation and the OSH Directives (including some references specific to the CMD) has been subject of an opinion of the 'REFIT Platform'[174] adopted on 27-28 June 2016.[175]

In their document the REFIT Platform recognises that the two sets of legislation are mutually reinforcing but points out that the interface between the REACH Regulation and OSH legislation is complex and that further clarification is needed. Furthermore, the ongoing review of the REACH Regulation revealed areas where improvements in the interaction of both areas can be made.

The concerned Commission services are working on providing clarifications and are together developing a common understanding approach on the interface between the REACH Regulation and OSH legislation as regards hazardous chemicals at the workplace.

Statut of the substances under the REACH Regulation

[172] Apart from 'non-isolated intermediates' which, during synthesis, are not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.
[173] Article 3(15) of REACH.
[174] The European Commission established the 'REFIT Platform' of Member State government and EU stakeholder representatives to support the simplification of EU law and the reduction of regulatory burden without detracting from the policy objectives of EU law.
[175] European Commission (2016): REFIT Platform Opinion. Available at: https://ec.europa.eu/info/files/refit-platform-recommendations-chemicals-ii2a-reach-osh_en

Table 86: Statut of the substances under the REACH Regulation

Acrylonitrile	
Restriction	Acrylonitrile use is restricted under Entry 28[176] of Annex XVII under the REACH Regulation. Substances listed under Entry 28 are not to be placed on the market for use by the general public 'when the individual concentration in the substance or mixture is equal to or greater than' either the 'relevant specific concentration limit' specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or the 'relevant generic concentration limit', specified in Part 3 of Annex I to Regulation (EC) No 1272/2008. Suppliers shall ensure before placing on the market that the packaging of such substances and mixtures is marked as 'Restricted to professional users'.
Authorisation	Acrylonitrile is not subject to authorisation according to Annex XIV of REACH.
Nickel compounds	
Restriction	Annex XVII of REACH entry 27[177] restricts the use of nickel and it compounds in jewellery (including watches) and articles intended to come into contact with the skin.
Authorisation	Nickel and its compounds are not listed in the Annex XIV of REACH ("Authorisation List"), therefore there are no authorised uses for nickel and its compounds.
Benzene	
Restriction	The following uses of benzene are restricted in entry 5[178] of Annex XVII: 1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005%) of the weight of the toy or part of toy. 2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market, or used, − as a substance, − as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0.1% by weight 4. However, paragraph 3 shall not apply to: a) motor fuels which are covered by Directive 98/70/EC6; b) substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation. c) natural gas placed on the market for use by consumers, provided that the

[176] https://echa.europa.eu/documents/10162/caa50aef-640d-43b6-8eb0-6c9c542afa70
[177] https://echa.europa.eu/documents/10162/7851171d-53e9-455a-8bb8-7ca22e89ad87
[178] https://echa.europa.eu/documents/10162/59f436ca-8afa-4adf-b108-27d7bc8a7751

	concentration of benzene remains below 0.1% volume/volume'.
Authorisation	Benzene is not listed on annex XIV of REACH, thus not subject to authorisation.