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Accompanying the document

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

amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates

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Glossary

ACSH	Advisory Committee on Safety and Health at Work
ALIPA	European Aliphatic Isocyanates Producer Association
BLV	Biological Limit Value
CAD	Chemical Agents Directive
CMRD	Carcinogens, Mutagens and Reprotoxicants Directive
CSS	Chemicals Strategy for Sustainability
DALY	Disability Adjusted Life Years
DNEL	Derived No Effects Level
DRR	Dose response relationship
ECHA	European Chemicals Agency
EFBWW	European Federation of Building and Woodworkers
EIG	Employers Interest Group of ACSH
ERR	Exposure Risk Relationship
EU	European Union
FIEC	European Construction Industry Federation
GIG	Government Interest Group of ACSH
ILA	International Lead Association
ISG	Inter-service group
ISOPA	European Diisocyanate and Polyol Producers Association
LAB	Lead acid batteries
NCO	Diisocyanate active group – Nitrogen, Carbon, Oxygen
NGO	Non-governmental organisation
OEL	Occupational Exposure Limit – 8 hour time-weighted average exposure
OSH	Occupational Safety and Health
PbA	Lead in air
PbB	Lead in blood
RAC	Risk Assessment Committee
REACH	Regulation on the Registration, Evaluation and Authorisation of Chemicals
RMM	Risk Management Measures
SDG	UN Sustainable Development Goal
SEA Europe	Shipyards' & Maritime Equipment Association of Europe
SME United	European Association of Crafts and SMEs
STEL	Short term exposure limit – normally time averaged over 15 minutes
SVHC	Substance of very high concern
TWA	Time-Weighted Average
WIG	Workers Interest Group of ACSH
WTP	Willingness To Pay

1. 1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

A strong social Europe calls for constant improvements towards safer and healthier work for all. Over the last years, the European Union (EU) occupational safety and health (OSH) policy framework and rules have contributed to considerably improving working conditions, in particular concerning workers' protection from exposure to carcinogens and other hazardous chemicals[1]. Exposure limit values and other provisions have been set or revised for many substances or groups of substances under the Carcinogens, Mutagens and Reprotoxic Substances Directive 2004/37/EC (CMRD)[2] and the Chemical Agents Directive 98/24/EC[3] (CAD).

Ensuring healthy and safe work environments is vital to protect workers, uphold productivity, and to allow for a sustainable economic recovery. The Commission announced in the European Pillar of Social Rights Action Plan[4] the intention to ensure a healthy, safe and well adapted work environment, which was confirmed with the adoption of the OSH Strategic Framework for 2021-2027[5]. Also, the 2020 Chemicals Strategy for Sustainability (CSS)[6] recognises the need to strengthen the protection of workers and identifies lead and diisocyanates among the priority chemicals to act upon.

The external stakeholder consultation on the evaluation of the previous EU OSH strategy for the period 2014–2020 confirmed that preventing work-related diseases is a common goal requiring coordinated actions including the need to continuously update binding occupational exposure limits (OELs)[7] [8].

Lead and its inorganic compounds (referred to throughout this report as 'lead') are key occupational reprotoxicants that can affect both fertility and the development of the foetus[9]. The current EU binding OEL is 0.15 mg/m³ and the biological limit value (BLV[10]) is 70 µg/100 ml blood. These were first introduced under a specific directive on lead in 1982[11] and have not been updated for over 40 years. They therefore do not take into account the latest scientific and technical developments and findings.

Diisocyanates are skin and respiratory sensitisers (asthmagens) that have the potential to cause occupational asthma and dermal occupational disease[12]. Currently there is no binding OEL or short-term exposure limit value (STEL[13]) for diisocyanates at EU level.

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[1] The EU OSH Strategic Framework on Health and Safety at Work 2014-2020, COM (2014) 332 final, 6.6.2014; the Commission Communication 'Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy', COM (2017) 12 final, 10.1.2017; the Commission Communication 'A strong social Europe for just transitions', COM(2020) 14 final, 14.1.2020, the EU Strategic Framework on health and safety at work 2021-2027, COM (2021) 323 final 28.7.2021.

[2] Directive 2004/37/EC .

[3] Directive 98/24/EC .

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52021DC0102&from=EN

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021DC0323&from=EN

[6] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021SC0149&from=EN

[8] OEL means the limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker in relation to a specified reference period, normally 8 hours.

[9] The reproductive health toxicity of inorganic lead compounds is due to their lead content. Therefore, a group approach is supported by the RAC to cover a broad range of individual lead containing substances.

[10] BLV means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect.

[11] Council Directive 82/605/EEC

[12] Diisocyanate substances have a common mechanism of inducing hypersensitivity mechanisms. Therefore, a group approach is supported by RAC to cover a broad range of individual diisocyanate substances.

The setting of limit values at EU level provides an objective measure that can be used to demonstrate effective control of risks to workers' health. Inadequate control of hazardous chemicals at the workplace has a negative impact on workers, and it is also associated with significant costs to individuals and society as a whole. Good OSH is essential not only to minimise ill-health but also associated costs[14].

This OSH initiative will contribute to the sustainable development goals (SDG) on good health and well-being (3rd goal), on decent work and economic growth (8th goal), on industry, innovation and infrastructure (9th goal) and on responsible production and consumption (12th goal).

When the preparatory work for this initiative started, both substances were in the scope of the CAD and the aim was to amend only this Directive. However, following the agreement in March 2022 between the European Parliament and Council during the fourth revision of the Carcinogens and Mutagens Directive (CMD) to extend its scope to reprotoxic chemicals, lead is now in the scope of the CMRD.[15] Consequently, the main legislative tools to ensure workers' protection against risks related to exposure to lead and diisocyanates are the CMRD and the CAD respectively.

In order to carry out this impact assessment, the Commission contracted a study[16] (referred to throughout this report as the 'external study') in order to collect the most recent information.

To support its work, the Commission requested a scientific evaluation by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) and an opinion of the tripartite Advisory Committee for Safety and Health at Work (ACSH). The opinions of the ACSH take into account the scientific basis and provide the Advisory Committee's view on feasibility factors, which are indispensable to underpin OSH legislation.

The Commission's analysis also takes into account views received through the different channels for consultation, including the formal two-stage consultation of the social partners and the views of stakeholders received in response to the call for evidence. In addition, the analysis takes into account the complementary benefits stemming from the recently adopted restriction under the Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH)[17] that requires the mandatory training of workers who may be exposed to diisocyanates. This contributes to the common aim of OSH and REACH to replace harmful chemicals by less harmful ones.

The purpose of this impact assessment is to assess whether there is a need to revise the level of protection offered by the CMRD and the CAD by revising the existing limit values for lead and to introduce, for the first time, a limit value for diisocyanates[18], as well as which would be the most appropriate levels to take forward. For more details on limit values, see Annex 7.

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[13] A STEL is usually referenced to a 15-minute period and is used when short duration exposures, such as peaks, are relevant to the onset of ill-health.
[14] https://www.prevent.be/en/knowledge/research-project-on-the-benefits-of-osh
[15] Directive (EU) 2022/431
[16] RPA (2021). Study on collecting information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents) and Directive 2009/148/EC (Asbestos).
[17] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20220501
[18] Diisocyanates is a collective term for a number of individual diisocyanates chemicals. This includes at least 25 different diisocyanates, of which 11 account for over 99% of the registered tonnage under REACH (ECHA 2019).

Box 1: Definitions of key technical terms

Occupational Exposure Limits
OELs are the limit of the Time-Weighted Average (TWA) of the concentration for a chemical in the air within the breathing zone of a worker in relation to a specified reference period (normally 8 hours).
Short Term Exposure Limits
STEL values, usually involving a 15-minute reference period, are used when adverse health effects are not adequately controlled by compliance with an 8-hour TWA OEL, e.g., for substances for which a critical effect is observed following a brief exposure (for example, acute toxic substances, substances causing nuisance, irritation, central nervous system depression, sensitisation).
Biological Limit Values
BLVs are the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect (in the case of lead, in the blood of the exposed worker).
Notations
OELs, STELs and/or BLVs can further be annotated with appropriate indications of additional body burden resulting from non-inhalation routes such as, for example, a 'skin' notation where the dermal route of exposure is scientifically considered to be relevant.

2. 2. PROBLEM DEFINITION

2.1 What is/are the problem(s)?

The 2017 ex-post evaluation of the EU OSH directives[19], including the CAD and the CMD, concluded that the directives remain highly relevant and effective according to the available evidence. It highlighted that limit values are an important tool for chemical risk management at the workplace and that there is a need to adopt exposure limit values for more substances of high concern, in particular carcinogenic, mutagenic and reprotoxic substances. Specifically, it identifies the need to consider the most appropriate approach to managing risks that may arise from exposure to reprotoxic substances, and if and how biomonitoring could be used more effectively for workplace risk management. It further states that sensitisers[20] should be considered as a high priority that merit further consideration to ensure that the risk management requirements are appropriate. However, whilst the evaluation identified the main issues, it did not provide the required detailed quantitative data.

This initiative is also in line with the stocktaking staff working document accompanying the EU strategic framework on health and safety at work 2021-2027 (SWD (2021) 148 final) which identifies the need to increase the focus on addressing occupational diseases. In particular, for lead it states that the limit values should be reviewed in light of new scientific data.

Lead is a key occupational reprotoxicant that can affect: i) sexual function and fertility and ii) the development of the foetus or offspring (developmental toxicity). Exposure to lead may result in impaired fertility, miscarriages, or serious birth defects, not to mention other harmful effects such as

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017SC0010&from=en
[20] Sensitisers can cause adverse reactions, including asthma, as a result of inhalation or absorption through the skin of a foreign substance to which the exposed person has been previously sensitised.

neurotoxicity, renal toxicity, cardiovascular effects and haematological effects. Lead accounts for around half of all occupational exposures to reprotoxic substances and associated cases of reproductive ill-health[21].

Diisocyanates are skin and respiratory sensitisers (asthmagens) that cause occupational asthma and dermal occupational disease – allergic reactions that can occur due to exposure to such substances. They can cause people's airways to change (the 'hypersensitive state'). Once the lungs become hypersensitive, further exposure to the substance, even at quite low levels, may trigger an asthma attack.

Studies have estimated that occupational factors account for approximately 9-15% of asthma cases in adults of working age[22]. Diisocyanates are one of the most common causes of occupational asthma with an estimated number of annual incidences of diisocyanate-related occupational asthma in the EU in the range from 2 350 to 7 269 cases [23] [24] [25].

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

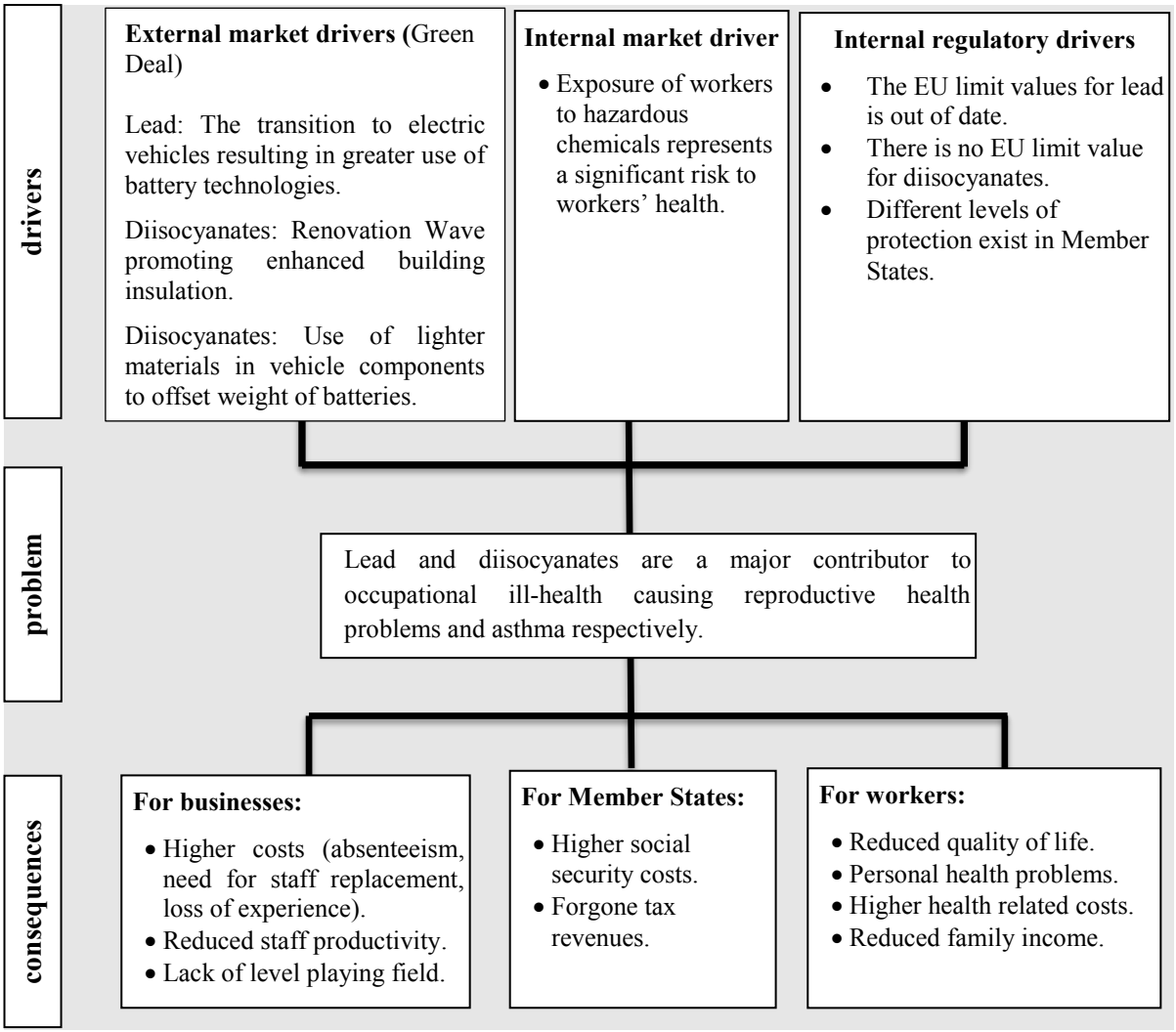
[21] Study on reprotoxic substances (2019) https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes

[22] Balmes J, Becklake M, Blanc P et al. (2003) American Thoracic Society Statement: occupational contribution to the burden of airway disease. Am J Crit Care Med. 167:787- 797.

[23] https://www.hse.gov.uk/statistics/causdis/asthma.pdf

[24] https://academic.oup.com/annweh/article/65/8/893/6247067

[25] As per footnote 16 -RPA study 2021 (external study supporting this Impact Assessment).



2.2 What are the problem drivers?

2.2.1 Internal market drivers

This section presents the uses and the estimated numbers of exposed workers per substance (more information is provided in Annex 5). 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.

2.2.1.1 Lead

Lead is currently used for a large variety of applications. In addition, workers may be exposed to lead at significant levels due to historic applications in activities such as renovation, waste collection, recycling and remediation[26]. It is estimated that approximately 50 000 to 150 000 workers in the EU are exposed to lead. Determining a precise number is difficult because workers in sectors such as demolition and

[26] The REACH Regulation prohibits the use of lead in paints, subject to certain derogation (Annex 8). However, workers may be exposed to lead when working on buildings and structures that were painted prior to the entry into force of the restriction.

waste management, and those using articles of lead metal may only occasionally be exposed to lead, but sometimes at relatively high levels. Approximately 300 cases of ill-health occur each year as a result of past occupational exposure to lead. This exposure is important due to the possibility of lead to accumulate in the bones, thus contributing to the overall body burden and likelihood of chronic ill-health.

The main sectors for industrial production and use of lead are primary and secondary lead production (including battery recycling); battery, lead sheet and ammunition production; production of lead oxides and frits; and lead glass and ceramics production. Exposure to lead is also possible in other industrial applications, such as foundries and production of articles of alloys with lead, and production and use of pigments for paint and plastics. Besides these applications, exposure may take place further downstream in the product chain and when the articles and materials become waste or during the waste recovery of recycled materials. Examples of downstream activities are applications of paints; shooting; work with lead metal; demolition, repair and scrap management; other waste management and soil remediation; and work in laboratories.

Company size is variable and is often sector specific. For example, there are: 6 primary lead production companies that are all large companies (more than 249 employees) and 30 lead battery manufactures, of which 80% are large and 20% medium sized companies. For most other sectors using lead, the companies are mainly SMEs.

The primary routes of occupational exposure are by inhalation and by ingestion by hand-to-mouth behaviour due to insufficient personal hygiene and housekeeping (e.g., a worker with contaminated hands who does not thoroughly wash them before eating or smoking). Dermal absorption of lead is considered to be minimal. Exposure by ingestion is considered significant and this exposure route is an important driver for the development of ill-health. Lowering the OEL is specific to inhalation exposure and additional measures are needed to minimise ingestion exposure. For that, blood lead concentrations are recognised as the best exposure metric to assess occupational exposures to lead, since internal lead levels are decisive for determining the overall risk to health.

Data indicates that the exposed workforce is predominantly male, especially in key sectors such as primary lead production, secondary lead production, lead battery production and lead sheet production (c.95-97%). The female workforce is around 3%, with the exception of lead crystal glass production (12%). However, the total size of the corresponding workforce is relatively small compared to the key sectors where lead is used. Even though the share of female workforce is relatively small, the gender dimension is very important. The negative impact of lead is double as it can affect women and, in addition, it affects the developing foetus in pregnant women[27]. There are existing requirements in the Pregnant Workers Directive[28]. However, they only apply from when the worker informs their employer that they are pregnant, typically three months into the pregnancy. Within the lead industry, awareness of workers of childbearing capacity and the need to have specific measures in place to minimise any possible risks is expected to already be an integral part of the employers' approach to risk management.

Compliance with the BLV is the primary tool for protecting workers from lead toxicity. Oral and inhalational exposure are both relevant routes for the uptake of lead into the human body. The OEL is needed to reduce the occupational exposure.

The relationship between levels of lead in air (PbA) and blood (PbB) depends on various factors within an occupational setting and an unambiguous correlation between these two metrics is not apparent.

[27] Lead can pass the placenta resulting in blood lead concentration in the umbilical cord at birth being close to the blood lead level of the mother (source: RPA, 2021 external study section 2.2.4.7).
[28] Council Directive 92/85/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31992L0085

Exposure occurs through multiple routes and even if the concentration of lead in the air is quite low, internal levels may still be relatively high, reflected by the biological monitoring results.

2.2.1.2 Diisocyanates

Diisocyanates are used in manufacture of polyurethane as both solids and foams, plastics, coatings, varnishes, two-pack paints and adhesives. Workers in companies manufacturing these materials are exposed, and so are workers using adhesives, sealants, paints and coatings containing diisocyanates. These products are widely used in construction, vehicle repairs, general repairs, textiles, furniture, and the manufacture of motor vehicles, other transport, domestic appliances, machinery and computers. Diisocyanates are transformed during the production process, and they are no longer present in the final manufactured product and, therefore, there is no risk to the user of the product (e.g., consumers). According to estimates[29], approximately 4.2 million workers are exposed to diisocyanates and more than 2.4 million companies in the EU are concerned, the vast majority being micro-enterprises or SMEs.

Currently, there are 19 individual diisocyanate substances registered under REACH. There is some variation in use between different diisocyanates. However, the three most produced diisocyanates (TDI, 4,4'-MDI and 2,4'-TDI) are all aromatic isocyanates and they have a similar use pattern which consists of, for example, flexible and rigid foams, adhesives and sealants. Aliphatic isocyanates (HDI and IPDI) are often present in coatings and paints. The health effects are caused by a common part of all diisocyanates (the NCO group[30]). Therefore, a grouping approach can be considered as it would allow for a common OEL and STEL for all diisocyanates[31]. This is in line with the grouping approach favoured by the recently adopted EU Chemicals Strategy for Sustainability.

The predominant health effects of occupational exposure to diisocyanates are respiratory health effects (occupational asthma, isocyanate sensitisation and bronchial hyperresponsiveness), which are the critical endpoints related to diisocyanate exposure occurring both after acute and long-term exposure. Peak exposures (short duration/high exposure levels) are a key influencing mechanism in the cause of occupational asthma. Therefore, a STEL, which best addresses repeated short-duration high-level exposures, is the most appropriate regulatory measure to address this type of exposure pattern. However, there is a lack of robust scientific information and socio-economic data on short-term exposures. For these reasons, RAC advised that any STEL should be maximally higher by a factor of 2 than the OEL and the external study could only analyse the impacts of the OEL.

In these situations, information on the safe use of diisocyanates and its correct application in real workplaces will be critical to ensuring effective control of workers' exposure whilst reducing the need for exposure monitoring and associated costs. This will be relevant for some, but not all, transient exposures in temporary workplaces such as construction. In part, this is addressed via the mandatory training requirements introduced by REACH for users of diisocyanates (see section 2.2.3.2).

The introduction of an OEL and STEL would provide quantitative objectives to concretise the intention of the general requirements of CAD. This is important for determining the type of risk management measures that should be introduced to ensure that exposure is effectively controlled. This aspect of the overall approach to risk management, based on the complementarity of CAD and REACH, is not specifically addressed by the REACH restriction, which is focussed on the training of workers.

[29] RPA, 2021. External study.
[30] The NCO group refers to the nitrogen, carbon, and oxygen atom of the isocyanate group.
[31] RAC and other scientific expert committees agree on an NCO grouping approach.

2.2.2 *External market drivers*

Lead battery manufacture is a key employment sector where workers may be exposed to lead. In 2017, the European Commission launched the European Battery Alliance[32]. Batteries are a strategic part of Europe's clean and digital transition and a key enabling technology, essential to the automotive sector's competitiveness. This aims to make Europe a global leader in sustainable battery production and use. This was followed by a proposal[33] to revise the Batteries Directive to minimise the negative impact of batteries and waste batteries on the environment, while ensuring the smooth functioning of the internal market.

Between 2010 and 2018, battery demand grew by 30% annually. The market is expected to keep growing, at an estimated 25% annual rate. The main drivers of demand growth are the electrification of transportation and the deployment of batteries in electricity grids[34]. In 2018, approximately 72% of the world rechargeable battery capacity was provided by lead-acid batteries (LABs). Approximately 65% of global demand for LABs is currently driven by automotive applications, with nearly every vehicle on the road currently requiring a LAB for starter, light and ignition functions.

Automotive lead batteries have a recycling rate of 99%, they are one of the few consumer products that already operate in a closed loop (i.e., where all used batteries are collected, and the component parts are recycled ready for reuse)[35]. Increasing demand for batteries and their recycling has the potential to increase the number of exposed workers.

For diisocyanates, the Renovation Wave Strategy under the European Green Deal[36] is likely to result in greater use of insulating foams and better surface coatings to enhance the thermal insulation of the built environment. In addition, the manufacturers of electric vehicles are increasingly considering replacing heavier materials in cars with polyurethane to offset the weight of batteries. Polyurethane coatings are also used in many applications including the rotor surfaces of wind turbines. Sectors manufacturing insulations foams and coatings, including their application, are key sectors using diisocyanates. Increasing demand for these products has the potential to increase the number of exposed workers.

2.2.3 *Regulatory drivers*

The CAD and the CMRD have as their aim the protection of workers against risks to their health, including the prevention of such risks, arising or likely to arise from exposure to hazardous substances at work, such as lead and diisocyanates. Since both substances are already covered by the Directives, the employer must assess the risks to workers' health for all activities in which workers are or may be exposed to lead or diisocyanates and apply appropriate risk management measures (RMMs) to ensure effective control of any identified risks. The limit values provide an important objective measure to facilitate the implementation of the Directives and improve the protection of workers by reducing the level of exposures.

For some hazardous chemical agents, the CAD and the CMRD establish limit values (OELs/STELs) and in the case of lead, a BLV. The fact that limit values are established does not affect the obligations of the employer to comply with other requirements which are based on the principles of good occupational hygiene practice, such as to minimise amount of substance in use, enclose

[32] https://ec.europa.eu/growth/industry/strategy/industrial-alliances/european-battery-alliance_en
[33] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0798
[34] A Vision for a Sustainable Battery Value Chain in 2030 (2019) https://www3.weforum.org/docs/WEF_A_Vision_for_a_Sustainable_Battery_Value_Chain_in_2030_Report.pdf
[35] https://www.eurobat.org/wp-content/uploads/2021/09/ihs_eurobat_report_lead_lores_final_2.pdf
[36] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0662

equipment/processes where possible to minimise release, maintain in good condition all risk management systems such as ventilation controls, train and inform workers on risks and safe working practices. The exposure must be reduced to a minimum and in any case below the fixed binding limit values when those exist.

In January 2019, the three Interest Groups (Workers', Employers' and Governments') of the Working Party 'Chemicals at the Workplace' (WPC) of the ACSH agreed that lead and diisocyanates are priorities for scientific evaluation by RAC. This is the first step in the process to revise the limit values for lead and to introduce, for the first time, limit values for diisocyanates[37]. The prioritisation of lead reflects growing concern about reprotoxic substances which resulted in their inclusion in the scope of the CMRD in early 2022. There is also a similar concern about how to tackle occupational asthma. Diisocyanates are one of a limited number of key occupational asthmagens. In addition, based on extensive stakeholder consultation, both substances were identified under the prioritisation strategy of the EU Human Biomonitoring programme (HBM4EU 2017-2018)[38], an EU Horizon 2020 initiative to build bridges between the research and policy worlds to enhance chemical safety.

Under the CAD and the CMRD, the Commission evaluates the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment, the availability of measurement techniques, and feasibility factors. The aim is to protect the health of workers by proposing appropriate binding limit values, including inhalation and biological limit values. New, or revised, limit values should be set on the basis of available information, including up-to-date scientific and technical data. This scientific evidence became available in June 2020 when RAC adopted its opinions on lead and diisocyanates[39] [40].

The Commission proposals for OELs also take into account scientific-technical feasibility of monitoring exposure, including the availability of suitable measurement techniques. Socio-economic and further technical feasibility factors are discussed in the WPC. More information on the procedure for setting limit values is presented in section 5.1. Technical and feasibility evidence was provided by the ACSH, which adopted opinions supporting this initiative for both substances on 24 November 2021[41]. For lead, there was not a consensus agreement between three Interest Groups of the ACSH on what the levels of any revised limit values should be. For diisocyanates, there was a consensus agreement of the three Interest Groups. The views of the social partners in response to the formal two-stage consultation and the responses to the call for evidence have also contributed to that evidence.

2.2.3.1 Lead limit values are out-of-date

For lead, the limit values in the CMRD are an OEL of 0.15 mg Pb/m³ and a BLV of 70 µg Pb/100 ml blood. They were first set in 1982[42] based on the scientific and technology knowledge available at that time. The directive further states that its minimum requirements should be reviewed based on experience acquired and on technology developments in the relevant areas.

[37] Minutes of WPC meeting held on 22-23 January 2019.
[38] https://www.hbm4eu.eu/hbm4eu-substances/2-prioritisation-process/
[39] https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037
[40] https://echa.europa.eu/documents/10162/4ea3b5ee-141b-63c9-8ffd-1c268dda95e9
[41] https://ec.europa.eu/social/main.jsp?catId=148&intPageId=683&langId=en
[42] See footnote 11.

The International Lead Association[43], representing companies across the EU engaged in mining, smelting and recycling have long established lead exposure reduction programmes introduced to meet the current limit values and to further reduce exposures, where achievable. This reduction of exposure over time demonstrates the effectiveness of limit values when combined with industry wide initiatives to implement practical risk reduction programmes.

The three ACSH Interest Groups reached a consensus agreement on the need to revise downwards both the existing BLV and OEL 'to better protect workers' health taking into account scientific and technical developments since the current limit values were adopted'. In their November 2021 opinion, they advise that oral and inhalation exposure are both relevant routes for the uptake of lead into the human body and that blood lead concentrations are the best exposure metric to assess occupational exposure. This is because internal lead levels are decisive for the chronic toxicity. Therefore, it is important to use the BLV as the primary tool for protecting workers from lead toxicity. The OEL and BLV complement each other, and both should be complied with.

For lead RAC proposed an OEL of 0.004 g /m^3 (equivalent to 4 µg /m^3) and a BLV of 15 µg/100ml blood (equivalent to 150 µg/L blood)[44]. A BLV of 15 µg Pb/100ml blood is considered health protective for male workers, who represent the vast majority of the total workforce exposed to lead, but not for the offspring of female workers of child-bearing age. RAC advised the inclusion of a qualitative statement in the CMRD that exposure of women of child-bearing age to lead should be avoided or minimised. There is agreement within the ACSH that a BLV of 15µg/100 ml is health protective for male workers but not for the offspring of female workers of child-bearing age.

The three Interest Groups did not find a consensus on what should be the numerical levels of the updated limit values (see Annex 2, table 1). The main reasons for this were the divergent views on how best to tackle workers with higher blood levels due to historic exposure, levels of exposure for women of childbearing age, and for the OEL, the uncertainties in the models used to derive the values and technical feasibility together with cost-benefit considerations to achieve these levels.

The three Interest Groups of the ACSH agree on the importance of health surveillance, which is already a requirement of the CMRD, for the effective management of all individual workers including those who may have been subject to historic exposure, or in the specific case of female workers who may wish to start a family. The general requirements for health surveillance (which apply to all substances within the scope of the Directive) are complemented by specific requirements when workers are exposed to certain specified levels of lead requiring more detailed medical surveillance when exposure exceeds 0.075mg/m^3 in air (50% of current OEL) or 40 µg/100ml blood (approx. 60% of current BLV). Health/medical surveillance is important because lead is stored in the bones for decades (half-life in bones[45] is 6 to 37 years) and released gradually into the bloodstream.

The International Lead Association (ILA) has produced a number of guidance notes[46] for reducing occupational exposure. They support the ILA Voluntary Blood-lead Reduction Programme and provide details on practical measures, e.g., regular health surveillance (biomonitoring) and practical advice/ideas regarding engineering controls. The actions under this voluntary initiative have shown that reductions in exposure are possible and are currently being achieved across several sectors. The ILA

[43] Resources – ILA (ila-lead.org) Position paper on protecting workers from occupational lead exposures (March 2022)
[44] For coherence with the current limit values in CAD, the metrics of g/m^3 for OEL values and µg/100ml blood for BLV values are hereafter used throughout this Impact Assessment Report.
[45] The time required for its concentration to decrease by half.
[46] International Lead Association: Guidance Notes. See at: https://ila-lead.org/resources/

Programme declared aim is to have zero employees exceeding a blood lead content of 20µg/100ml (i.e., well below the current BLV). Industry voluntary initiatives reflect technical progress and demonstrate that the reduction of workers' exposure is both technically possible and feasible.

2.2.3.2 There is no EU limit value for diisocyanates

The opinion of the ACSH supports the introduction, for the first time, of an EU OEL and STEL for all diisocyanates based on the NCO group approach. The limit values should be complemented by a 'skin' notation in order to prevent systemic health effects due to absorption from dermal contact. The three Interest Groups agreed on the numerical values of the OEL and STEL that should be proposed and advised that a phase-in approach is required due to technical measurement feasibility and the time to implement RMMs, in particular in downstream sectors.

Diisocyanates do not have a safe exposure level; only the relation between exposure levels and the associated risk can be described (exposure-risk relationship). Therefore, RAC presented a set of excess risks for a range of OELs between 0.025 and 0.67 µg NCO/m^3. RAC also stated that the value of STEL should be no more than twice that of the OEL, and it should not exceed 6 µg NCO/m^3.

Employers, in their response to the second stage social partner consultation, highlighted the need to tackle the problem of occupational asthma by preventing peak exposures. They recognise the need to take a pragmatic approach to setting the STEL that will significantly reduce peak exposures resulting in a major improvement of workers' health.

Due to the nature of asthma, specific health surveillance is appropriate in line with Articles 6.3 and 10 of the CAD to identify early signs and symptoms of respiratory sensitisation. These arrangements should be in accordance with national laws and/or practice, as well as in line with the principles and practices of occupational medicine.

Under the CAD there are general requirements for the training of workers, but this is not substance specific. Therefore, due to the need to address the identified serious health risks specific to diisocyanates, a restriction under REACH was adopted in August 2020[47]. The restriction requires the mandatory training of workers who use diisocyanates, in accordance with specified criteria linked to the nature of the work activity. This aims to prevent occupational asthma by reducing exposure by the application of good working practices. The training must be in place by August 2023.

The introduction of limit values for diisocyanates under CAD together with the existing general requirements of the directive in conjunction with the restriction under REACH will provide a comprehensive complementary package of regulatory measures to ensure an overall effective risk management approach. This package includes workplace risk assessment, introduction and use of effective risk management measures, worker information, comprehensive training and supervision, and appropriate health surveillance.

2.2.3.3 Differing levels of protection

Acknowledging the development of the scientific knowledge, some EU countries have already reduced their limit values for lead to a varying degree and/or introduced limit values for diisocyanates. Therefore, workers in the EU are subject to different levels of protection.

For lead, EU countries' BLVs range from 20µg/100ml blood to 70µg/100ml blood (the current BLV under the CMRD). 15 Member States have a BLV lower than the current EU BLV48. Some Member

[47] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R1149
[48] BG, HR, CZ, DK, FI, FR, DE, HU, IT, LV, NL, PL, SK, SI, SE.

States have a lower limit for women. This is age dependent or stated as women of childbearing age and typically ranges between 20-40 µg/100ml blood. The OEL ranges from 0.05 g/m3 up to 0.15 g/m3 (the current OEL under the CMRD).

For diisocyanates, whilst there is no EU limit value, three EU Member States have a general OEL[49] and18 have different OELs and STELS for some, but not all, different diisocyanates. As regards the STEL, 17 Member States have a STEL of which only 5 have a general STEL; the others are for specific diisocyanates substances. This makes presenting a general range challenging. However, where they exist, OELs range from 3 µg NCO/m^3 to 500 µg NCO/m^3 with a median value of 17.4 µg NCO/m^3. For the STEL, the range is from 10-82 µg NCO/m^3.

2.2.4 Consequences

In addition to the above identified issues for workers (ill-health, differing levels of protection), Member States are also negatively affected. The resulting illnesses lead to increased social security costs (e.g., through higher costs for medical treatment and work incapacity) and missed tax revenues.

Ineffective prevention of exposure to lead and diisocyanates also entails negative consequences for businesses, as companies that do not take appropriate measures may have a competitive advantage over those who do. In the longer term, the consequences of ineffective prevention on businesses will eventually result in higher costs from reduced productivity due to absenteeism and loss of expertise.

2.3 How will the problem evolve?

2.3.1 General

In the absence of EU action, it is estimated that workers exposed to these chemicals will continue to face the risk of occupational ill-health. Estimations of the numbers of ill-health cases and their associated health costs over a 40-year period in case no action is taken are contained in the baseline scenario.

The general obligations set by the CAD and the CMRD, employers' actions and measures adopted by Member States contribute overall to lowering exposure. 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 processes, or for specific lead or diisocyanate substances, and in the future the numbers of workers in the industries using these chemicals may also change, and technological developments could facilitate lower exposure concentrations.

Future forecasts for both substances are however far from certain due to scarcity of relevant data. For that reason, assumptions are based on the legal provisions contained in the CAD and the CMRD, including the exposure elimination and minimisation requirements, but also on other data including information gathered from the stakeholders.

2.3.2 Lead

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. The first

[49] HR, IE, LT.

signs of lead blood level reduction take a minimum of two to three months to become visible, depending on previous levels, effectiveness of measures and biological parameters.

Data on exposure concentration trends from various sources[50] show that blood lead levels have reduced drastically during the past decades but appear to have stagnated in recent years. Continuous efforts within the main lead producing and processing sectors indicate that further reductions are likely, however, these are not reflected in the exposure concentration trend data of the most recent years. In view of that stagnation, exposure concentrations are assumed to be stable for the future years in the below calculations.

Available information does not suggest exposure concentration reduction in other sectors than the main lead producing and processing sectors for the recent years. The key sectors and uses of lead include mining of lead ore (8 Member States), refining of ore (18 Member States) and subsequent production and use of lead containing products, for example in the construction and battery manufacturing sectors. Exposures may also occur in the demolition, renovation, repairing and scrap industry and also during recycling of articles due to historical use of lead in paints, electronic equipment and plastics.

The 'Renovation Wave'[51], with a focus on making the buildings more energy-efficient and sustainable, will accelerate the renovation works of the EU building stock. The Strategy aims to double the annual energy renovation rates by 2030. This could result in an even greater number of workers exposed to lead in the near future, for example, during the removal of lead containing paints, plumbing and roofing materials.

Based on market projections for lead batteries, Eurobat expects the numbers of workers in the industry to be similar for the next 10 years. From 2030 and beyond, there will be significant changes to the automotive market in terms of electrification and replacement of the internal combustion engine, as part of the European Green Deal goal of reaching carbon neutrality by 2050, and it is not clear which role the lead battery will play in this transition. Lead batteries are currently used for ancillary purposes in electric vehicles and there is no data to indicate that this will change in the near future. In addition, the proposal for the new Batteries Regulation sets targets for key scarce resources such as lead. This includes a target date of 2030 for 90% material recovery and 2035 for a minimum share of recovered lead of 85%. This is a recognition that the use of lead batteries will continue beyond 2035.

The same applies to industrial batteries where increased energy density will be required for many storage applications resulting in the need for a more diverse range of available battery technologies[52].

The external study predicts around 12 000 cases of adverse health effects and 1 400 cases of developmental toxicity[53] over a period of 40 years and for a workforce of 98 850.

2.3.3 Diisocyanates

The use of diisocyanates is expected to steadily increase in the future across many sectors. Diisocyanates can be used in several ways within and on buildings. More than 220 million building

[50] Lead REACH Consortium 2015-2018 and 2013-2016 surveys, Voluntary Risk Assessment Report for lead (2008), as well as national data from Germany (2020), Finland (2013), Romania (2019) and UK (2019).
[51] See footnote 36
[52] https://www.eurobat.org/wp-content/uploads/2021/09/ihs_eurobat_report_lead_lores_final_2.pdf
[53]The study focussed on the most relevant illnesses per category of adverse health effects. For non-cancer illnesses, it estimated the cases of neuropathy (neurological effects), chronical kidney disease (renal effects), elevated blood pressure (cardiovascular effects), anaemia (haematological effects), as well as male infertility, pre-eclampsia and developmental toxicity (reproductive effects). For cancer, it estimated the expected number of brain cancers.

units, representing 85% of the EU's building stock, were built before 2001 and are/will be renovated (either for maintenance purposes or for energy costs savings) or demolished and replaced by new construction. The Renovation Wave Strategy under the European Green Deal (external market driver), with a focus on making the buildings more energy-efficient and sustainable, will accelerate the renovation works of the EU building stock. The renovation of existing buildings and construction of new buildings will result in an increase in the use of modern high efficiency insulation materials[54].

Energy efficient insulation and an extensive range of building techniques depend on polyurethane, adhesives, sealants and coatings that use diisocyanates. There is a risk of exposure related to the handling of insulation and foam materials during new build and renovation work.

The projections for renovation under the Renovation Wave Strategy are for a 1% annual energy renovation rate for 2021-2022, an increase to 1.2% per year in 2023-2025 before stabilising at, at least, 2% per year in 2026-2029. The Commission estimates the potential for an additional 160 000 green jobs in the construction sector in the EU by 2030.

In addition, manufacturers of electric vehicles are increasingly considering replacing heavier materials in cars with polyurethane to offset the weight of batteries. Sophisticated polyurethane coatings are also used in many applications including the rotor surfaces of wind turbines. Another example of potential growing demand is the wood sector for use in adhesives due to regulatory pressures on existing substances used in wood adhesives such as formaldehyde.

In general, the global demand for diisocyanates is growing[55] as they become used in more sectors and as their end products are used by a growing European population. However, there is also a continual trend to automate industrial processes, particularly those with higher potential for exposure, and therefore the number of exposed workers is expected to be static in future years.

It is estimated that approximately 5 000 cases of asthma and 1 300 cases of irritation will occur each year and if no further action is taken. This is predicted to continue over the next 40 years due to exposure during this period. The estimated number of cases takes into consideration the anticipated effect of the REACH Restriction, which was introduced in 2020 and comes into effect in 2023. The REACH Restriction introduces specific training requirements for workers using diisocyanates. These requirements complement the general training requirements under EU OSH legislation.

3. 3. WHY SHOULD THE EU ACT?

3.1 Legal basis

Article 153 of the Treaty on the Functioning of the European Union (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.

[54] Exposure to asbestos can occur during the renovation of existing buildings. This occupational risk is addressed via a separate initiative to lower the OEL for asbestos fibres in Directive 2009/148/EC.
[55] Statista (2022) available at: https://www.statista.com/statistics/750818/tdi-demand-worldwide/

The protection of workers' health against risks arising from exposure to lead and diisocyanates is already covered by EU OSH legislation, in particular by the CMRD and the CAD, as well as under the REACH Regulation. The change of scope of the CMD resulting from the adoption of the CMRD brings lead, a reprotoxic substance, under the CMRD.

3.2 Subsidiarity: Necessity and added value of EU action

Scientific knowledge about lead and diisocyanates has developed since the adoption of the CAD, in 1998 (and the previous 1982 directive specific to lead). In order to ensure that the measures for protecting workers from exposure to lead and diisocyanates are as effective as possible, the Directives need to be kept up to date with that knowledge. Updating the CAD and the CMRD to take account of newer scientific evidence is an effective way to ensure that preventive measures would be updated accordingly in all Member States.

Both substances are broadly used in a wide range of sectors and countries. This supports the added value of EU action due to the problem being widespread across the whole EU.

For lead, the external study identifies 18 Member States that produce refined lead and a more limited number of them mining lead. The production rate of lead in the EU is in excess of 10 million tonnes per year used for a broad range of processes including lead battery, sheet and powder production, use in articles etc. The voluntary initiatives of the ILA described above, whilst welcome, are non-binding and not all employers or sectors are members of organisations to which they apply.

For diisocyanates, they are manufactured in seven Member States and used throughout the EU in 21 relevant downstream sectors.

Significant divergences between national limit values distort competition in the internal market. 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 limit values. For lead, companies based in Bulgaria, Czechia, Denmark, Latvia and Poland need to comply with an OEL 3 times lower than the maximum OEL set at EU level (0.050 g/m^3 vs 0.15 g/m^3). As for diisocyanates, in the absence of an EU limit value, differences are larger. Where national limit values exist, OELs range from 3 $\mu g\ NCO/m^3$ to 500 $\mu g\ NCO/m^3$.

The revision of existing, and the introduction of new exposure limit values under the CAD and the CMRD will lead to a greater harmonisation of limit values across Europe. Thus, while individual Member States could still introduce lower values, and further improve the protection of workers as aimed by both Directives, the level playing field for enterprises will improve[56]. Companies willing to operate in the different EU Member States can further benefit from a streamlining of the applicable limit values, potentially providing savings as common solutions can be adopted across facilities, as opposed to designing site-specific solutions to meet different limit value requirements.

Furthermore, the revision or introduction of limit values is very complex and requires a high level of scientific expertise. An important advantage of the adoption of the limit values 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 improving further the OSH policies in each Member State.

[56] The harmonisation of limit values across the EU would contribute to a level playing field for enterprises. The closer the EU OEL gets to zero, the lower the scope for divergences across Member States is.

Therefore, for both lead and diisocyanates, action at EU level it is both necessary and adds value. Amending the CAD and the CMRD can only be done by action at EU level.

4. 4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1 General objectives

This initiative contributes to the improvement of health and safety of workers pursuant to Article 153 of the TFEU[57] [58]. It aims at ensuring workers the right to a high level of protection of their health and safety at work, as laid down in principle 10 of the European Pillar of Social Rights[59], and to prevent deaths caused by work-related cancer and other health problems according to the second key objective of the EU Strategic framework on health and safety at work 2021-2027.

For the substances addressed by this analysis this is to be achieved by reducing occupational exposure to lead and diisocyanates in the EU.

4.2 Specific objectives

The specific objectives are:

1. To enhance the effectiveness of the occupational limit values for lead under the CMRD on the basis of scientific and technical knowledge;
2. To enhance the effectiveness of the CAD by introducing limit values for diisocyanates;
3. To achieve a more balanced and effective protection of workers across the EU against lead and diisocyanates thereby contributing to a reduction in the burden of occupational ill-health.

The specific objectives of the initiative contribute to the sustainable development goals on good health and well-being (3rd goal) and on decent work and economic growth (8th goal). A positive impact is also expected for the SDG on industry, innovation and infrastructure (9th goal) and on responsible production and consumption (12th goal).

4.3 Consistency with other EU policies

4.3.1 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[60].

4.3.2 Coherence with the REACH Regulation

The REACH Regulation[61], in force since 2007, establishes among others two distinct EU regulatory approaches that are restrictions and authorisations.

[57] OJ C 115, 9.5.2008, p. 114–116
[58] OJ C 326, 26.10.2012, p. 391–407
[59] See footnote 4
[60] OJ C 326, 26.10.2012, p. 391–407

The applicable provisions of REACH restriction of lead and diisocyanates, are as follows (see Annex 8):

4. A number of uses of lead are restricted under REACH. This includes the use of lead in paints with some exemptions[62] [63], the use of lead and its compounds in jewellery and articles which are intended to come into contact with the skin, and the use of lead and its mixtures supplied to the general public are forbidden[64].

5. Diisocyanates are restricted under REACH[65] and shall not be used or placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional uses unless the employer or self-employed ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the substance(s) or mixture(s).

The ACSH, in its opinion, stated that a combination of the REACH restrictions (on worker training) and OSH provisions, especially limit values and health surveillance, is the most efficient approach for preventing peak exposure, which is the key event leading to asthma from exposure to diisocyanates.

Together, the EU OSH directives (CMRD & CAD) and the REACH Regulation are relevant for workers' protection from the risks of exposure to lead and diisocyanates.

4.3.3 Coherence with the Batteries Regulation

The Commission proposed a new Batteries Regulation[66] in December 2020 with the aim to ensure that batteries placed on the EU market are sustainable and safe throughout their entire life cycle. This is an integral part of the EU Green Deal which aims for greater use of modern non-fossil fuelled vehicles for which increased use of lead-containing batteries, including their recycling, is expected. The proposal for the new Batteries Regulation sets targets for key scarce resources such as lead. This includes a target date of 2030 for 90% material recovery and 2035 for a minimum share of recovered lead of 85%. This recognises that the use of lead-acid batteries will continue beyond 2035. The updating of the limit values for lead under the CMRD ensures workers in this sector will benefit from a high level of health protection and contributes to addressing the risk from hazardous substances which were identified as a social risk in the Batteries Regulation proposal.

4.3.4 Coherence with scientific research

Lead and diisocyanates were priority chemicals under the EU human biomonitoring programme (HBM4EU) funded by Horizon 2020[67]. This was a joint effort of 30 countries, the European Environment Agency and the European Commission, that ran from 2017 to 2021. It generated knowledge to inform the safe management of chemicals and so protect human health.

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[61] See footnote 17
[62] https://echa.europa.eu/documents/10162/22dd9386-7fac-4e8d-953a-ef3c71025ad4
[63] https://echa.europa.eu/documents/10162/ffd7653b-98cc-4bcc-9085-616559280314
[64] https://echa.europa.eu/documents/10162/61845f2b-f319-ab2e-24aa-6fc4f8fc150f
[65] https://echa.europa.eu/documents/10162/503ac424-3bcb-137b-9247-09e41eb6dd5a
[66] https://ec.europa.eu/environment/pdf/waste/batteries/Proposal_for_a_Regulation_on_batteries_and_waste_batteries.pdf
[67] https://www.hbm4eu.eu/about-us

4.3.5 Coherence with Europe's Beating Cancer plan

The aim of Europe's Beating Cancer Plan is to tackle the entire disease pathway[68]. It is structured around four key action areas where the EU can add the most value: (1) prevention; (2) early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors. Whilst the main adverse health effects resulting from exposure to lead are on reproductive health, in rare cases it could cause cancer, and the reduction in limit values would contribute to preventing this cancer.

For diisocyanates the adverse health effects do not include cancer and the Europe's Beating Cancer plan is not relevant.

5. 5. WHAT ARE THE POSSIBLE POLICY OPTIONS?

5.1 Process for setting binding limit values under the CAD and the CMRD

A simplified outline of the process for the development of EU limit values, including OELs, STELs and BLVs, for priority substances is set out here, with a more detailed description in Annex 7.

As mentionned in Chapter 1, the selection of the specific two groups of 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 two groups of substances are of high relevance for the protection of workers. The Commission's intention to prepare for the establishment of new or revised limit values for those priority substances was confirmed and encouraged by all the stakeholders.

5.2 Baseline Scenario

The baseline or "no policy change" option includes all relevant EU-level and national policies and measures (e.g., the existing national limit values) which are assumed to continue being in force in the absence of further EU action. It also takes into account the variables discussed in previous sections, such as the current number of workers exposed and its evolution over time, the current and future exposure levels, the current RMMs, the voluntary industry initiatives, the development of new technologies and any other substance-specific relevant factors (e.g., the REACH restriction for diisocyanates).

5.2.1 Lead

EU wide OEL of 0.15 mg/m³ and a BLV of 70 µg Pb/100 ml blood, dated from 1982 (and carried forward in 1998 in CAD and transferred to the CMRD in 2022) will remain.

[68] https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf

5.2.2 Diisocyanates

Currently there is no EU level OEL or STEL. Consequently, in the absence of EU levels, divergences in protection levels across Member States will continue.

The REACH restriction requiring specific training of workers using diisocyanates will come into effect in August 2023. The impact of the REACH restriction is likely to be significant in reducing asthma. Following discussions with experts in the steering group for the external study, it was agreed that the restriction will result in reducing airborne concentrations of diisocyanates by 50%.

Regarding changes at industry level, the experts in the steering group for the external study considered that, while the growing automatisation of processes should decrease exposure, the growth in the use of diisocyanates[69] would compensate that effect. Some of those growing uses are linked to the efforts made in the framework of the Green Deal to use lighter materials to offset the weight of batteries in electric vehicles and in the framework of the Renovation Wave to enhance energy savings via better building insulation. Based on the available information, it is not possible to give a more specific prediction of future trends. Therefore, the baseline assumes a continuation of the exposure levels and the number of exposed workers.

The summary of the baseline scenario is presented below.

Table 1: Baseline scenario over 40 years

	Lead	**Diisocyanates**
Types of ill-health caused	Neuropathy, anaemia, chronic kidney disease, elevated blood pressure, male fertility, pre-eclampsia, developmental toxicity (effects on the foetus; IQ loss)	Asthma, irritation
No. of exposed workers	98 850	4 226 583
Change in future exposure level	No changes	Differs per sector
Change in future no. of exposed workers	No change	No change
Current disease burden (CDB) - all historic exposures for current types of exposure situations (estimated)	1 331 cases per year (combined total for all types of ill-health of which 1 154 are chronic kidney disease)	Asthma 5 125 cases per year Irritation 1 315 cases per year
Future disease burden (FDB) - for current types of exposure situations (estimated)	13 379 (combined total for all types of ill-health)	Asthma 106 910 over 40 years Irritation 10 099 over 40 years
Monetary value FDB	€317 million – 612.7 million Present Value (PV) over 40 years	Asthma: €3.9 billion – €7.2 billion PV over 40 years Irritation: €7.4 million – €10.4 million PV over 40 years (Both after REACH Restriction)
Based on external study: RPA (2021) *Workforce turns over at 5% p.a.		

[69] In 2021, the global demand for TDI was some 2.49 million tons, up from 2.37 million tons in 2020 (5% increase) and from less than 2 million tons in 2016 (source Statista (2022), available at: https://www.statista.com/statistics/750818/tdi-demand-worldwide/).

5.3 Options discarded at an early stage

5.3.1 Phasing out the use of lead

The phasing out of the use of lead was not considered as a realistic policy option. This is because the use of this substance remains necessary for a number of critical purposes in a range of sectors including construction activities and in batteries for fossil fuel and electric vehicles. For the latter, lead based batteries are necessary for non-motive purposes (such as information systems) and for safety to allow the vehicles to be brought to a stop in case of an emergency[70].

The CMRD does not allow for the banning of substances. Instead, it places duties on employers to protect workers by aiming to substitute harmful substances by the less harmful and, where this is not possible, to prevent exposure. Where this is not technically possible, employers have the duty to implement risk management measures following a hierarchy of control that requires the use of technical measures (such as process enclosure or ventilation) with preference to the use of personal protective equipment (such as overalls, gloves, respiratory protection).

In addition, a banning on the future use of lead would not benefit workers who may be exposed due to past use of lead. For example, when removing lead containing paint from surfaces prior to re-painting with modern lead-free alternatives, or for workers in waste management who may be exposed to lead from discarded items.

In the case where a ban would be considered necessary, it would be more appropriate to do this as a restriction under REACH, for which there are several examples including the banning of lead in paint.

5.3.2 Guidance documents

As non-regulatory alternatives, the existing guidance documents or examples of good practice could be revised and re-disseminated in cooperation with the European Agency for Safety and Health at Work (EU-OSHA) and/or the ACSH and its relevant Working Party. This could also include the launching of awareness raising campaigns for employers and workers alike on the prevention of risks arising from workers' exposure to lead and to diisocyanates. In addition, industry could be encouraged to revise guidance material used to support their voluntary initiatives.

However, guidance documents by themselves would not be considered effective enough in reaching the objectives of this initiative. They are complementary and provide an added value to OELs/STELs/BLVs. Guidance on good practice is of particular importance when addressing peak exposures to diisocyanates during transient activities such as certain construction tasks.

EU-OSHA is currently developing guidance on the use of biomonitoring at the workplace. This will be general guidance and not specific to lead, though the general principles will be relevant and helpful.

5.3.3 Adapted measures for SMEs

Small companies, accounting for around 99% of companies working with lead and diisocyanates, should not be exempted from the scope of the initiative. Their exclusion would mean that the vast majority of European workers at risk of exposure to these groups of substances would not be sufficiently protected by health and safety at work legislation, with a clear distortion and inequality in

[70] Consortium for Battery Innovation | » How lead batteries make EVs safer https://batteryinnovation.org/how-lead-batteries-make-evs-safer/

the application of the EU legislative framework and with a risk of compromising the underlying social policy objectives and fundamental rights.

Another option to assist SMEs is to extend the implementation time the limit value. This has been considered for diisocyanates to take account of the need to adapt industrial processes. Based on discussions with stakeholders, including the ACSH, a similar approach was not agreed for lead.

5.4 Policy options

In addition to the baseline scenario, options for different limit values -OELs, STELs and BLVs-, are presented below. They take into account the scientific assessments done by the RAC of ECHA, the adopted opinions from the ACSH and the limit values in place in the different Member States (see Annex 5).

The external study provided a comparison of the costs and benefits for a range of potential OELs and BLVs. The ranges start at the values proposed by RAC.

Throughout the analysis of benefits and costs, the reference levels in tables 2 and 3 have been chosen as the options of the assessment. The external study considered a number of additional intermediate reference levels and assessed their corresponding impacts. To streamline the presentation of the analysis, they are not retained in this report.

5.4.1 Lead

Table 2: BLV options for lead

Options	Level, µg/100 ml	Reason for inclusion
Option 1 (baseline)	70	Existing EU level.
Option 2	20	Lowest national BLV in EU Member States for all workers (Denmark). Voluntary target of International Lead Association.
Option 3	15	BLV at the level proposed by RAC.
Option 4	4.5	Biological guidance value related to background exposure of the general population. Applies to women of childbearing age (under 50 years of age).

The detailed analysis of the impacts concerns lowering the BLV from 70 to 20, 15 and 4.5 µg/100ml. Setting the BLV at 0 µg/100ml is not a realistic option due to background exposure of the general population from non-occupational sources of exposure such as dietary intake.

In addition to lowering the BLV, it is necessary to lower the OEL. Since blood lead levels are recognised as the main exposure metric in assessing occupational exposures, most companies focus on blood levels management and found it challenging to provide data on airborne levels management. As stated in the ACSH opinion, the relationship between the levels of lead in air and blood depends on

various factors within an occupational setting and an unambiguous correlation between these two metrics is not apparent.

Therefore, it is not possible to identify OEL options and to independently assess their impacts with any degree of certainty. However, the RMMs used to reduce blood levels will reduce airborne ones and, considering the views of key stakeholders in the ACSH opinion, a numerical value for the revised OEL is presented as a preferred option to complement the BLV. In its opinion, the three Interest Groups of the ACSH did not reach a consensus on what the numerical levels of the updated limit values should be. Whilst the Governments' and Employers' Interest Groups supported a BLV of 15µg/100 ml, the Workers' Interest Group favoured a limit value of 4.5µg/100 ml (for more details, see Annex 2). The preferred option takes into account the assessment of the impacts of the options assessed for the revision of the BLV. Whilst imprecise, this is considered to be an acceptable way forward by the ACSH.

5.4.2 Diisocyanates

Table 3: OEL options for diisocyanates

Options	Level, µg NCO/m^3	Reason for inclusion
Option 1 (baseline)	-	No existing EU level
Option 2	10	Agreed by study steering group members
Option 3	6	Agreed by study steering group members
Option 4	3	This is numerically half the maximum STEL recommended by RAC who also recommended the STEL is at most two times the OEL

The external study assessed a broader range of options, including options below 3µg NCO/m3. This information on lower options was available to the ACSH when they agreed on the limit values recommended in their opinion. Since the ACSH adopted its opinion by consensus supporting an OEL of 6 µg NCO/m3, the options retained for the analysis were selected to represent a realistic range of possible limit values at, above and below the value recommended by the ACSH.

An OEL defined as an 8-hour TWA exposure based on the 'NCO group' can be obtained from the Exposure Risk Relationship (ERR) for hyperresponsiveness or diisocyanate asthma as derived below, based on excess risk over a working life period.

A 15-minutes STEL value is required since peak exposures are important and drive the onset of asthma. However, measuring peaks in epidemiological studies is not practically possible and for this reason, RAC focussed on the OEL whilst concluding on the need for a STEL that should be determined using a multiplication factor of no more than two times the OEL. Based on its scientific evaluation including the exposure risk relationship, RAC recommended that the STEL should not exceed 6 µg/m^3 NCO and that it should be no more than two times the OEL. This takes into account availability of scientific data, which is not fully conclusive and is subject to expert scientific opinion based on associated excess risk levels with different exposures. It is consistent with accepted practice whereby there is a factor between the OEL and the STEL. In this specific case, RAC considered a factor of 2 to be appropriate. The details of this approach are presented in the RAC Opinion. This is taken into account in the assessed policy options.

RAC states that any limit value will be associated with a residual risk since it is not possible to identify a safe threshold of exposure at which there is no risk. Based on the ERR, all of the assessed options are associated with an excess risk of developing occupational asthma over a working life. RAC further advised that the lower the exposure, the lower the risk for developing asthma.

Whilst this analysis focusses on the OEL, it should be noted that the control measures necessary to ensure compliance with the OEL will also contribute to controlling short term exposures. An explicit separate assessment of STEL levels is not possible due to a lack of appropriate data on short-term exposures. Since the lack of scientific data limits the possibilities for an assessment of the health benefits of the different STEL options for diisocyanates, the projections related to costs are also impacted. The likely underestimation of the costs and benefits does therefore not allow for a purely quantitative comparison. This is developed further below in section 6.1.

Moreover, RAC considered that notations for skin sensitisation, respiratory sensitisation, 'skin' were warranted. The notations indicate that in addition to the need to control inhalation exposure, it is important to prevent dermal exposure as the substance can be absorbed through the skin and contribute to overall exposure and elicitation of asthma. This can be achieved, for example, by the wearing of gloves and coveralls.

6. 6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

6.1 Analytical methodology

The revision of the limit values for lead and the introduction of an OEL and a STEL for diisocyanates is expected to result in a reduction in the occupational exposure to both these hazardous chemicals. 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 (the "baseline scenario").

For a given reduction in exposure levels, the expected decrease in the incidence of ill-health over 40 years was calculated. This required estimating the risks of adverse health effects, derived from the existing toxicological and epidemiological literature, as well as information about the current level of worker exposure (number of workers exposed, level, duration and frequency of exposure). The calculations of ill-health cases and the cost-related calculations are based on a 40-year reference period, in order to take into account the total risk over the working life. This allows to present a long-term view, instead of considering only the risks that might manifest at the early stages of exposure.

The health benefits of the revised OEL/STEL/BLV are calculated in terms of the costs of ill-health avoided. They have been expressed in monetary terms by applying standard valuation methods, in line with the Better Regulation Toolbox guidance. Method 1 is the application of a single willingness to pay (WTP) value to each case and Method 2 is the use of disability adjusted life years (DALYs) and their monetisation. Both estimates monetise the same number of avoided cases and use identical methods for the monetisation of direct (healthcare, informal care, disruption for employers) and indirect

(productivity/lost earnings[71]) impacts but use different approaches to assign monetary values to intangible effects (reduced quality of life, pain and suffering, etc.).

The estimate of the costs was made based on a literature research and data obtained from stakeholders and take into account the following factors: the RMMs [72] needed to comply with the proposed limit values, the costs of these RMMs for each company, the life span of the RMMs and the number of companies.

The benefits and costs of possible limit values are measured against the baseline, meaning that only marginal costs and marginal benefits are taken into account (i.e., additional costs imposed by the different OEL scenarios on top of those that businesses would already have to bear under the baseline in order to comply with their existing obligations).

The calculations in the report are subject to certain methodological limitations. Regarding lead, exposure concentrations, the number of workers and their turnover are key determinants of the costs and benefits. A sensitivity analysis was performed to simulate a higher and lower value for each of those three factors. In general, costs-benefit ratios did not change significantly for the two first. Only in the case of worker turnover (as it affects only the calculation of the benefits) did that ratio improve (higher turnover) or decrease (lower turnover) more significantly.

For diisocyanates, the main methodological limitation impacting the robustness of projections is the lack of scientific data to assess the health benefits of the different options. Whilst peak exposures are particularly important in the development of occupational asthma[73], related ill-health cases could not be modelled due to a lack of data on short-term exposures (see section 5.4.2). This results in an underestimation of the costs and a significant underestimation of the benefits (asthma accounts for more than 90% of the future disease burden) and the impossibility to calculate the impact of the different STEL options in terms of ill-health cases avoided. Consequently, it does not allow for a purely quantitative comparison of the options. Another source of uncertainty is the assumed impact of the REACH restriction. However, due to the difficulties regarding the calculation of the benefits, the sensitivity analysis performed is less straightforward than in the case of lead.

More information about the analytical methodology is available in Annex 4.

6.2 Social impacts

6.2.1 Health impacts for workers and families

Lead

Table 4 presents the number of avoided cases of ill-health as well as monetised benefits. For the endpoint developmental toxicity, the effects are in the form of IQ loss of newborns.

[71] This is not the case where lost earnings are already taken into account in the willingness to pay estimate in published literature.
[72] E.g., engineering and ventilation controls, cleaning, personal hygiene, personal protective equipment.
[73] The RAC opinion states that there are indicators that peak exposures are important for the risk of asthma development. However, measuring peaks in human epidemiological studies is not practically possible because of measurement difficulties.

Table 4: Number of avoided cases of ill-health by endpoint over 40 years for each BLV policy option (compared to baseline)

Endpoint	Option 2 (20 µg/100ml)	Option 3 (15 µg/100ml)	Option 4 (4.5 µg/100ml)
Central nervous system cancer	4	6	6
Neuropathy	179	290	290
Anaemia	1 381	1 645	2 009
Chronic kidney disease stage 1	4 273	5 085	6 208
Elevated blood pressure	1 969	2 365	2 912
Male fertility	310	387	491
Pre-eclampsia	16	23	38
Developmental toxicity (total IQ loss)	370	540	1,141
Total number of avoided ill health cases	8 502	10 341	13 095
Health benefits of avoided ill health cases due to revised BLV in monetary terms over 40 years*.	€130 million - €200 million	€160 million - €250 million	€200 million - €310 million
* *Standard valuation method. Lower value Method 1, higher value Method 2*			

Source: RPA, 2021. External study

All options substantially improve the protection of workers, with option 4 having the most substantial impact on number of avoided ill health cases. The health benefits in monetary terms are presented as a range as they depend on the methodology used. The benefits would be slightly higher under options 3 and 4 but significant progress would be made under each option.

Gender is an important factor. Even though the share of the female workforce is relatively small (around 3%), lead can affect the developing foetus in pregnant women. RAC mentions in its opinion that option 3 (and option 2 by analogy) does not protect from developmental toxicity. Consequently, it suggests to avoid any exposure of women of childbearing age. Against this background, option 4 would offer a better protection to these women by preventing almost all pre-eclampsia cases and about 80% of developmental toxicity cases.

Diisocyanates

Table 5 presents the number of avoided ill-health cases under each option. However, and as highlighted in section 6.1, the ill-health cases associated with peak exposures could not be calculated due to a lack of scientific data. This leads to a significant underestimation of the ill-health cases, especially since peak exposures are particularly important in the development of occupational asthma, the main endpoint.

Table 5: Number of avoided cases of ill-health by endpoint over 40 years for each OEL policy option (compared to baseline)

Endpoint	Option 2 (10 µg NCO/m^3)	Option 3 (6 µg NCO/m^3)	Option 4 (3 µg NCO/m^3)
Asthma	0	0	50
Irritation	0	0	259

Source: Study team

Reducing cases of asthma and irritation would, in theory, require an OEL set at 3 µg NCO/m^3 (option 4) or lower[74]. Monetised benefits of option 4 are estimated between EUR 0.8 and EUR 2.2 million. As the calculations could not take into account ill-health cases associated to peak exposures, options 2 and 3 would, according to the model, have no positive impacts on the number of ill-health cases against the baseline scenario. However, although not possible to calculate, it can be anticipated that by reducing average and peak exposures, benefits would materialise at options 2, 3 and 4 levels. Therefore, we can conclude that options 2, 3 and 4 will lead to a more significant improvement of the protection of workers than what it is reflected in the table.

6.2.2 Impacts on employment

Lead

The negative consequences on employment are only expected under option 4 as 29 companies (out of which 25 are small or medium-sized enterprises) would discontinue their activities[75], in particular in the sectors of foundries and demolition, repairing and scrap industry. About 1 800 workers[76] in the EU would lose their job, which would represent an estimated cost of EUR 150 million for workers and their families. It cannot be excluded that some of these workers could find work in companies offering lead-free alternative solutions in the same sectors. However, it was not possible to quantify these possible transfers due to a lack of data.

No discontinuation is expected under options 2 and 3. More information on the companies which would discontinue under option 4 is provided in section 6.3.2.

Diisocyanates

There are no negative impacts on employment expected under options 2 and 3. Under option 4, about 50 companies (almost all small companies) operating in textiles and apparel sectors would close down due to excessive impacts on their activities. Around 100 workers in the EU are expected to lose their jobs, which would represent an estimated cost of EUR 8.5 million for workers and their families.

[74] Based on the STEL being numerically twice the level of the OEL, this would result in a STEL of 6 µg NCO/m3 (value recommended by RAC).
[75] A company is expected to discontinue when the cost of the risk management measures is higher than the cost of discontinuing.
[76] 300 workers in secondary lead production, 840 in lead battery production, 92 in production of articles of lead metal, 400 in foundries, 105 in ceramic ware production and enamelling, 13 in work with lead metal and 27 in demolition, repairing and scrap industry.

6.3 Economic impacts

6.3.1 Impact on businesses, including SMEs

Lead

The direct costs for businesses (table 6) depend exclusively on the costs of the necessary RMMs to comply with a stricter EU limit value for lead ('compliance costs'). Since companies already have to demonstrate compliance with the existing EU limit values for lead and perform health surveillance according to the requirements in the CAD, it is not expected that they will face additional monitoring or administrative costs.

The additional compliance costs (compared to the baseline) are increasing with the stricter values. They are estimated at EUR 348 million (option 2), EUR 745 million (option 3) and EUR 6.3 billion (option 4). About 22 500 companies (99% of them small or medium-sized enterprises) would have to bear those additional costs under all options. The costs per company (over 40 years) would vary on average from EUR 15 000 to EUR 300 000 depending on the policy option. Under options 2 and 3, the compliance costs would represent less than 1% of the annual turnover. Under option 4, the share would be between 1% and 3% and would affect in particular small and to a lesser extent medium-sized enterprises operating in some sectors[77].

The companies will also have benefits related to improved labour productivity, lower costs of sick leave and other administrative and legal costs (e.g., linked to the replacement of employees). They are expected to vary from EUR 5 to EUR 6 million.

All the Member States, with exception of Denmark[78], would have to lower their existing limit values under any of the options. Therefore, almost all the companies in the EU would be affected in a similar way. A wide variety of sectors are particularly represented in France, Germany, Italy, Poland and Spain, in which the existing limit value is higher than option 2. Therefore, these Member States are expected to be more affected under each policy option.

More details per sectors and Member States are provided in section 6.3.2.

Table 6: costs and benefits for businesses (in € million, over 40 years)

	Option 2 (20 µg/100ml)	Option 3 (15 µg/100ml)	Option 4 (4.5 µg/100ml)
Costs			
Compliance costs	€350	€750	€6,300
Monitoring costs	€0	€0	€0
Administrative costs	€0	€0	€0
Benefits			
Avoided costs	€4	€5	€6

[77] Secondary lead production (including lead battery recycling), production of articles of lead metal, foundries, production of lead compounds and lead frits and ceramic ware production and enamelling.
[78] Denmark has a national limit value of 20 µg/100ml.

Diisocyanates

Compliance costs

Under option 2, companies would not face additional compliance costs compared to the baseline scenario. The measures currently in place should be sufficient to keep the workers' exposure under this limit value.

In the case of options 3 and 4, however, there will be additional compliance costs (table 7) due to additional investment in risk management measures (RMMs). This would entail investing in local exhaust ventilation systems (requiring high one-off and low recurrent costs). On the other side, both these options would also lead to savings, as the new ventilation systems will reduce the need to use respiratory protective equipment (characterised by low one-off and high recurrent costs).

Under option 3, only companies operating in manufacture of textile and wearing apparel sectors (less than 1% of the total number of companies with exposed workers) would need to invest in additional RMMs. The costs will be approximatively EUR 10.5 million over 40 years (EUR 3.3 million [manufacture of textile] and EUR 7.2 million [wearing apparel]). This net cost over 40 years takes into account EUR 4.4 million savings due to a reduced use of respiratory protective equipment. This also means that companies in those two sectors would have to bear upfront EUR 15 million, which would represent approximatively EUR 1 425 per company.

Under option 4, companies operating in several sectors would have to invest about EUR 830 million in new RMMs over 40 years. In the decreasing order of total costs, the sectors are maintenance and repair of motor vehicles, manufacture of wearing apparel, manufacture of textile, manufacture of chemicals, and repair and installation of machinery and equipment. However, the costs per company are expected to be particularly high for companies operating in textile and wearing apparel sectors (EUR 8 200 and EUR 4 300 respectively) compared to the others (between EUR 0 and EUR 3 100). These costs represent only 0.05% of companies' turnover, but the necessary investments would be made almost entirely from day 1. Overall, the companies most impacted would be small and medium-sized enterprises, which usually have less capital for investment.

Monitoring costs

65% of companies operate in 19 Member States with existing OELs and STELs for at least one diisocyanate (in particular MDI or TDI). However, it is expected that those with low exposure levels usually do not measure it as it is not strictly required in certain Member States. The remaining 35% of companies are assumed not to carry out any measurement at the moment since they operate in Member States with no limit values.

The monitoring of the OEL and STEL is assumed to be carried out at the same time. Therefore, the costs of administration, planning, execution and reporting are shared. Only costs related to sample/filter and analysis are specific to OEL or STEL.

Under option 2, it is assumed that 50% of the companies operating in a Member State with no limit value[79] will start monitoring workers' exposure. This means around 435 000 (431 500 small, 2 950 medium and 620 large) companies that would in total spend EUR 4.6 billion on monitoring over 40 years. The costs per company according to their size over 40 years would be EUR 10 351 (small),

[79] Eight Member States have neither an OEL nor a STEL: CY, CZ, EL, LU, MT, NL, PT, SK.

EUR 32 922 (medium) and EUR 182 041 (large). For companies in Member States with an existing limit value for one or several diisocyanates, no additional costs are expected.

Under options 3 and 4, 75% of the companies in Member States without a limit value are assumed to start monitoring workers' exposure. The number of concerned companies and the monitoring costs will therefore be the same under both options. In total, about 1 million companies (1 million small, 7 100 medium and 1 500 large companies) would dedicate EUR 11 billion over 40 years for monitoring workers' exposure, which represents EUR 11 265 per company over 40 years.

Administrative costs

The cost of planning, executing and reporting the sampling and analysis of monitoring is carried out by an external specialised company and considered therefore as compliance cost. However, although this task is externalised, some staff still have to manage the monitoring carried out by the external company. The spending related to this management is an administrative cost. Since larger companies have to monitor the exposure of more workers than SMEs, it is assumed that more time and/or resources have to be mobilised. Based on the estimates, large companies would spend EUR 22 230 over 40 years for managing the externalised monitoring while small and medium-sized companies would dedicate EUR 2 223 and EUR 11 115 respectively, over the same reference period.

Benefits

Establishing an EU-wide OEL and STEL for diisocyanates would also bring benefits to companies in the form of cost savings, depending on their values. A decrease in the number of ill-health cases would lead to less sick leave, increased labour productivity, reduced administrative and legal costs (e.g., when finding replacements for sick staff). Under options 2 and 3, no monetised benefit could be estimated as the avoided ill-health cases could not be quantified. Regarding option 4, only businesses operating in the textile and apparel sectors would save about EUR 0.4 million over 40 years).

Total costs and benefits

Most of the costs for companies derive from the obligations to monitor the workers' exposure, representing about 80% of the total costs for each option. Under option 2, businesses would spend more than EUR 5.5 billion over 40 years. Under options 3 and 4 they would have to spend EUR 13.4 billion and EUR 14.2 billion respectively. Since the monitoring and administrative costs are equivalent for options 3 and 4 (EUR 13.4 million), their difference lies in the risk management measures' costs (EUR 10 and EUR 830 million respectively). Although businesses would save some expenses under option 4, these are too limited to be considered as mitigating the costs.

On average, a company would spend EUR 2 300 under option 2, EUR 5 550 under option 3 and EUR 5 887 under option 4. Since most of these costs are related to monitoring tasks, they are spread over the 40-year reference period. Therefore, companies would bear annual costs ranging from EUR 57.5 to EUR 150 depending on the option retained.

While the average yearly cost per company is limited, companies operating in textiles and apparel sectors would have to spend between EUR 4 000 and EUR 8 000 in RMMs from day 1 to comply with an OEL at the level of option 4. Since more than 97% of those companies are small enterprises, some of them might face difficulties to bear those incremental costs. It is estimated that about 50 SMEs would cease their activities under option 4. No plant closures are expected under options 2 and 3.

More details per sectors and Member States are provided in section 6.3.2.

Table 7: costs and benefits for businesses (in € million, over 40 years)

	Option 2 10 µg NCO/m³	Option 3 6 µg NCO/m³	Option 4 3 µg NCO/m³
Costs			
Compliance costs	€0	€10	€830
Monitoring costs	€4,600	€11,000	€11,000
Administrative costs	€1,000	€2,400	€2,400
Benefits			
Avoided costs	€0	€0	€0.4
Source: RPA, 2021, External Study			

6.3.2 Impact on the single market

<u>*Lead*</u>

All the companies should be financially robust enough to comply with an EU BLV at the level of options 2 or 3, but some could face more difficulties under option 4. The discontinuation of activities by companies is calculated based on the cost of the RMMs in relation to the turnover and profit margin for an individual enterprise. The discontinuation cost is taken as the loss of profit taken over 20 years and the average profit is assumed to be 10% of turnover. More details on the methodology used to estimate discontinuation can be found in Annex 4, section 2.1.5 on the methodology.

Amongst the options analysed, discontinuations would only occur with a BLV of 4.5 µg/100ml. Indeed, the estimates show that 29 companies (of which 25 are small or medium-sized enterprises) in eight sectors[80] would discontinue their activities if the limit value is brought down to 4.5 µg/100ml. The ceramic ware production and enamelling sector would be particularly affected. It is assumed that 11.6% of enterprises with exposed workers in those two sectors would exit the market under option 4. 75% of the companies in those two sectors are based in Spain and Italy. Furthermore, between 5% and 8% of the companies with exposed workers in the following sectors would also exit the market under option 4: secondary lead production (including lead battery recycling), lead battery production, production of articles of lead metal and foundries. While we do not have figures about foundries, between 43% and 60% of the companies operating in the first three sectors are based in Germany, Italy or Poland. The consequences on the employment of enterprise closures are discussed in section 6.2.2. The costs to comply with option 4 are significant and would lead companies in some sectors to dedicate more than 1% of their turnover to RMMs. About 75% of these compliance costs are one-off costs, which means that companies wishing to enter the market would face a significant increase in capital costs to invest when setting up the business. Consequently, it is expected that revising the limit value for lead at the level of option 4 would increase market entry barriers, in particular for the sectors referred to in footnote 74. On the contrary, the impact of reducing the limit value to the level of option 2 or 3 would not be significant.

The compliance costs will also have a negative impact on companies operating in sectors where lead-free alternative products are available (e.g., ceramic frit, alloys, crystalline glass). Although it is not possible to quantify this impact, those enterprises competing with lead-free products will be less cost competitive, particularly under option 4, since they would bear high compliance costs.

[80] Secondary lead production (including lead battery recycling), lead battery production, production of articles of lead metal, foundries, ceramic ware production and enamelling, work with lead metal, shooting ranges, and demolition, repairing and scrap industry.

Revising downward the existing limit value for lead would increase harmonisation across the EU, as Member States can only adopt limit values equal or lower than the EU one. This would have a positive impact on the level playing field for companies across the internal market. Under option 3 or option 4 almost all Member States would have the same limit value.[81] Medium and large companies with facilities across the EU could in particular benefit from the regulatory simplification arising from this increased harmonisation.

Diisocyanates

Under all policy options, the total costs over 40 years for companies would not represent a significant share of their total turnover. Only small companies active in the repairs, apparel, vehicle repair, specialised construction and textile sectors would have to dedicate between 0.1% and 0.2% of their turnover to comply with an OEL (and its associated STEL) set at the level of option 4, which remains relatively bearable. Therefore, the impact on companies using diisocyanates compared to the others not using them in a same sector should be very limited.

About 50 companies (mainly small enterprises) active in textiles and apparel sectors would close down under option 4. They represent only 0.03% of the market for the two sectors (0.5% when considering only companies with workers exposed to diisocyanates) and therefore no significant impact on competition within the single market is expected. The other two options would not have any impact on competition.

Although some sectors (textiles and apparel) could be characterised by higher costs under option 4, they are not as significant as to impact new entrants compared to existing firms. Since costs for companies are lower under options 2 and 3, the same observation applies.

The introduction of both an OEL and a STEL for diisocyanates will improve the functioning of the single market by reducing disparities across Member States. To date, eight Member States in the EU have no OELs and STELs for any kind of diisocyanates. Most of the remaining 19 Member States have OEL or STELs for a few diisocyanates only, which are higher than those explored in this impact assessment. Therefore, setting an OEL and a STEL for all diisocyanates and a lower level than what it is currently in place in a majority of Member States will entail a more harmonised legal framework within the EU. In particular, companies operating or wishing to operate in more than one Member State would benefit from a less fragmented internal market. They will save on both research costs and design costs through facilitating the adoption of common solutions to reduce exposure across plants in different locations.

6.3.3 Indirect economic impacts

Lead

This section relies on a qualitative assessment due to a lack of data. **Research and development (R&D)** are key activities in an industry's capacity to develop new products and produce existing ones more efficiently and sustainably, in a way that protects the safety of workers. The ability to engage in R&D activities is likely to be affected by the availability of financial resources to invest in R&D; the availability of human resources to conduct R&D activities; and regulatory environment conducive to investing in R&D activities. Compliance costs, particularly under option 4, will have an impact on enterprises' capacity to innovate, as the research and innovation budget is likely to be partly diverted to invest in RMMs.

[81] Unless they decide to set a more stringent limit value.

Consumers may be impacted if higher costs for enterprises increase their prices. Since the costs for businesses under options 2 and 3 are estimated not to be significant, the impact on consumers should be very limited. Under option 4, companies could be tempted to pass on a part of the compliance costs to the consumers. However, most of the sectors are characterised by a high degree of competition; therefore, this is unlikely to happen. For the sectors of primary lead production, production of lead compounds and copper production, the costs will likely be passed on to consumers, owing to a moderate to high market concentration.

The impacts on **international competitiveness of EU companies** would significantly vary depending on the option. The impacts on international competitiveness of EU companies under options 2 and 3 would be limited and moderate. A substantial number of EU sectors and enterprises pursue a voluntary limit value of 20 µg/100ml (same as option 2). .Only three non-EU countries have a binding BLV in place for lead, which range between the existing EU BLV and the proposed revised EU BLV (see Annex 5), most of them have an OEL (according to the assessment, it would correspond to a BLV of 30 µg/100ml). The impacts under option 4 could be substantial as the companies operating in the EU would have to deal with much higher compliance costs than companies outside the EU. This said, both shooting ranges and demolition, repair and scrap sectors would not be impacted on the international stage since their activities are exclusively executed on EU territory, requiring compliance with the EU rules. The companies operating in those sectors account for 80% of the EU enterprises with exposed workers to lead. For the preferred option, the impact on competitiveness for companies working with lead should be moderate, although these costs could not be quantified

Diisocyanates

Any additional costs arising from the setting of an OEL and STEL at the EU level could in theory impact companies willing to invest in **research and development (R&D)**. According to estimates, expected R&D expenditures of small companies over 40 years would be lower than the total costs for businesses related to the setting of an OEL over the same period under the three policy options. The stricter the OEL, the higher the number of impacted small companies. Although those small companies would probably not dedicate all their R&D budget to the incremental compliance costs, those additional costs could negatively weight on their capacity to invest in R&D. When it comes to medium and large companies, the total costs are usually much lower than the expected R&D expenditures. Therefore, the expected impacts are much more limited and would not be significant.

The impact on **consumers** should be very limited. The number of companies with workers exposed to diisocyanates is between 150 and 2 500 000, depending on the sectors. Only two sectors count less than 1 000 companies. All these sectors are therefore highly competitive and mature, and therefore the incremental costs, which are limited under each policy option, will not easily be passed on to consumers. In addition, no closures are expected under options 2 and 3, which means that they will not have any influence on the structure of the market or on the level of competition therein. Under option 4, textiles and apparel sectors could be impacted by the closure of about 50 companies. However, since they represent a very limited share of the total number of companies (around 2 500 000), the impact should not be significant.

The setting of EU-wide OEL and STEL for diisocyanates could potentially undermine the **international competitiveness** of the companies based in the EU. The main competitors of the EU have higher limit values in place than those explored in this impact assessment. However, those countries often have different compliance rules and methods to define exposure, which makes the comparison difficult. Furthermore, since most of the companies in the different sectors are small and medium-sized enterprises (ranging from 88% to 99.9%), it is likely that they do not have existing plants in third countries and operate on a national scale only. Therefore, those companies do not have

incentives to transfer their activities outside the EU in view of benefiting from less costly rules for the protection of workers. Furthermore, companies operating in the construction and vehicle repair sectors (representing more than 50% of the total companies) are usually not subject to international competition due to the nature of the work. Finally, the total costs incurred by each of the policy options considered in this impact assessment report are limited and should therefore not have an impact on the competitiveness of the EU at international level.

6.3.4 Impact on public authorities

As both substances are already in the scope of the respective Directives, additional enforcement costs are expected to be zero. National authorities are responsible for inspecting companies to check if they are in compliance with the legal requirements already in the national OSH legislation transposing EU directives. The limit values are only one of the requirements of the Directives and not the one triggering inspections.

Neither the CMRD nor the CAD contain any obligations for companies to notify public authorities of their use of substances covered by these Directives, including lead and diisocyanates. Instead, the checks for compliance by national authorities take place during the regular inspections. Therefore, public authorities would not bear any additional costs linked to the processing of received notifications. Besides, no notification costs are foreseen resulting from any need for public authorities to notify the European Commission of their work to transpose the Directives, or of results of conducted inspections to companies. The transfer of such information to the European Commission is carried out in the framework of the reports on the practical implementation of the EU OSH Directives, submitted by the Member States to the Commission every five years, in accordance with Article 17a of Directive 89/391/EEC. As a result, there are no notification costs for any of the options. As explained in section 6.9, notification costs thus are not subject to offsetting in the context of the 'one in, one out' approach.

Lead

The benefits to the public authorities are composed of avoided costs of treatment (healthcare treatment costs borne by public authorities) and increased tax revenues. Costs to the public authorities will include transposition measures to introduce the updated limit values in their national legislation.

Whatever the option, most of the Member States would need to bear the costs related to the transposition of the new limit values, approximatively EUR 500 000[82] (table 8). However, those costs would be largely compensated by the benefits under each option. These benefits would vary from EUR 90 to EUR 130 million depending on the option retained.

Table 8: Costs and benefits to taxpayers/public authorities – lead (compared to baseline)

	Option 2 20 µg/100ml	Option 3 15µg/100ml	Option 4 4.5 µg/100ml
Benefits (avoided costs of ill health)	**€90 000 000**	**€100 000 000**	**€130 000 000**
Transposition cost	**€500 000**	**€520 000**	**€540 000**
Net benefit (benefits – costs)	**€89 500 000**	**€99 480 000**	**€129 460 000**
Source: External study calculation, for EU 27			

[82] Transpositions costs per Member State are estimated to be of EUR 20 000.

Diisocyanates

Since no Member States have an OEL and a STEL currently in place at the level of each policy option, all of them will need to carry out a transposition under each option. In the 19 Member States having already an OEL or STEL for one or several diisocyanates set in their legislation, the cost to revise it is estimated at EUR 30 000 for the transposition. For eight Member States without any OEL or STEL, the cost estimated is EUR 50 000. EU Member States will dedicate in total EUR 970 000 to the transposition under each of the options explored in this impact assessment.

Member States will also benefit from setting limit values at the EU level due to reduced healthcare costs. They would save about EUR 1 million under option 4, while the estimated benefits are null under options 2 and 3. Those estimates are likely to be underestimated since peak exposures could not be calculated, leading to an underestimation of the ill health cases.

Setting an OEL and a STEL at EU level enables to carry out one single impact assessment and scientific opinion rather than 27, one in each Member State. Savings are estimated at about EUR 1 750 000. They range from EUR 50 000 to EUR 100 000 depending on whether the Member State already has an OEL or a STEL in place or not.

In conclusion, the benefits for public authorities outweigh the costs under each option: EUR 1 780 000 for option 4 and EUR 780 000 for options 2 and 3.

Table 9: Costs and benefits to taxpayers/public authorities – diisocyanates (in comparison to baseline)

	Option 2 10 µg NCO/m³	Option 3 6 µg NCO/m³	Option 4 3 µg NCO/m³
Benefits	**€1 750 000**	**€1 750 000**	**€2 750 000**
Transposition cost	**€970 000**	**€970 000**	**€970 000**
Net benefit (benefits – costs)	**€780 000**	**€780 000**	**€1 780 000**
Source: External sStudy calculation, for EU27			

6.4 Impacts on the environment and on climate change

Lead

Lead can naturally originate from the mineral bedrock that formed the soil. Natural background concentrations are difficult to determine, since lead pollution has been going on for a long time. Anthropogenic sources of lead in soil include the formerly used lead-containing petrol, mining operations, metal processing as well as production, use and disposal of lead-containing products like lead-acid batteries, lead sheets etc. Also, lead-containing ammunition have been deposited at or near shooting ranges. Thus, soils in urban and industrial areas have increased concentrations of lead.

Emissions from point sources to air, soil and water are reported in the European Pollutant Release and Transfer Register. About 500 facilities reported lead emissions in 2017, emitting an estimated total of 260 tons, with main contributions from the energy sector (mainly thermal power stations and other combustion installations) and metal production and processing (lead mining, smelting and refining). The main emission is to the air (ca. 200 tons).

Alternative RMMs, due to comply with a stricter limit value may help to marginally improve environmental exposure to lead (e.g., when a more efficient extraction system would better capture lead

dust). However, significant differences are unlikely to be recognised compared to the current situation. In any case, these alternative RMMs will not result in additional negative impacts.

Reducing the limit values for lead is not expected to have an impact on climate change, though greater use of lead batteries in, e.g., electric vehicles will contribute to a reduction in the use of fossil fuels.

Diisocyanates

Diisocyanates are a group of synthetic substances and do not have natural sources. Most diisocyanates are not considered as having persistent qualities. They are highly reactive and when released into an environment containing water (for example, in relation to air, aquatic environments, and soil) diisocyanates produce a polyurea crust which is insoluble and inert. In practical terms this means that there is no direct risk to the environment from unreacted diisocyanates. For the same reasons bioaccumulation of diisocyanates is not considered possible. Based on the above there is no identifiable significant impact on the environment.

A greater use of insulating material based on diisocyanates will improve the thermal insulation of buildings with a consequent reduction in the use of fossil fuels for heating, thus contributing to mitigating climate change. This will not be directly impacted by the introduction of limit values.

6.5 Impacts on fundamental rights

All options align with the EU Charter of Fundamental Rights. Article 31 of the Charter states that workers have the right to fair and just working conditions that respect their health, safety and dignity. This is further developed in the European Pillar of Social Rights[83] which aims to build a fairer and more inclusive European Union. The initiative for lowering the OEL/BLV for lead and for introducing an OEL/STEL for diisocyanates will thus have a direct positive impact on fundamental and social rights, as it will further improve the protection of workers from the health risks posed by exposure. Taking into account the avoided ill-health following the implementation of new, or revised, limit values, the respect of these rights will also be positively impacted.

6.6 Contribution to sustainable development

The initiative will contribute positively to sustainable development goals on good health and well-being (3rd goal) and on decent work and economic growth (8th goal). A positive impact is also expected for the SDG on industry, innovation and infrastructure (9th goal) and on responsible production and consumption (12th goal).

6.7 Impacts on digitalisation

None of the policy options for both lead and diisocyanates would have any impacts on digitalisation.

[83] https://ec.europa.eu/info/strategy/priorities-2019-2024/economy-works-people/jobs-growth-and-investment/european-pillar-social-rights_en

6.8 Administrative impacts

As explained in sections 6.3.4, neither the CMRD nor the CAD contain any notification obligations.

For **lead**, public authorities could incur administrative costs if, for example, they have to do more reporting to the EU or there are other additional administrative burdens. However, no additional reporting is anticipated and any other administrative burdens for Member States' authorities than those already referred in table 8 could not be identified and, therefore, quantified.

For companies, since all the options considered in this impact assessment are about revising existing limit values, such a revision would not introduce any additional administrative requirements. Therefore, the administrative costs for companies are null under each option.

Many activities are performed by companies working in one Member State only (micro-enterprises and SMEs). However, several larger and to lesser extent medium-sized companies with facilities in different Member States would benefit from administrative simplification, owing to a more harmonious set of compliance requirements. Due to the lack of data, a quantification of those administrative savings was not possible.

As for lead, none of the options explored for diisocyanates should entail additional administrative burdens for Member States. The possible revision of the CAD would be limited to the setting of an OEL and a STEL, with no additional requirements such as new reporting activities for public authorities.

For companies, as described above, some costs are expected. Large companies would spend EUR 22 230 over 40 years while small and medium-sized companies would dedicate EUR 2 223 and EUR 11 115 respectively, over the same reference period. This brings the total for all companies to €2.4bn for the whole 40-year period, as indicated in table 11 below.

6.9 'One in, one out' approach

The administrative costs for companies operating with diisocyanates relate to the inspection on behalf of public authorities and are therefore not subject to offsetting in the context of the 'one in, one out' approach[84]. Companies manufacturing or using lead will not face any additional administrative costs as explained in the previous subsection. Therefore, there are no administrative costs to be offset according to the 'one in, one out' approach.

6.10 Summary of the impacts

The tables below provide a summary of the different impacts by policy options for both lead and diisocyanates.

Lead

Table 10: Multi-criteria analysis on lead (all impacts over 40 years and additional to the baseline)

Impact	Stakeholders affected	BLV options (µg/100ml)		
		Option 4: 4.5	Option 3: 15	Option 2: 20

[84] Better Regulation Tool #58 'EU Standard Cost Model'.

Impact	Stakeholders affected	BLV options (µg/100ml)		
		Option 4: 4.5	Option 3: 15	Option 2: 20
Direct costs – compliance				
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€6 300 million	€750 million	€350 million
Monitoring (sampling and analysis)	Companies	€0	€0	€0
Direct costs - administrative burdens				
Company cost of additional administration	Companies	€0	€0	€0
Direct costs — total per company				
Compliance and monitoring costs per company	Companies	€300 000	€31 000	€15 000
Direct costs - enforcement costs				
Transposition costs	Public sector	€520 000	€500 000	€480 000
Enforcement costs	Public sector	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0
Adjudication costs	Public sector	€0	€0	€0
Indirect costs – other				
Firms exiting the market - No. of company closures	Companies	29	0	0
Employment – Jobs lost	Workers & families	1 800	0	0
Employment – Social cost	Workers & families	€150 million	€0	€0
International competitiveness	Companies	Substantial negative impact	Moderate negative impact	Limited negative impact
Consumers	Consumers	Limited impacts expected		
Internal market	Companies	Lowest/ highest BLV from 4.5 to 4.5	Lowest/ highest BLV from 10 to 15	Lowest/ highest BLV from 10 to 20
Specific MSs/regions - MSs that would have to change BLVs	Public sector	All MS	All MS	All MS
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited		
Direct benefits – improved well-being – health				
Reduced cases of ill health (all endpoints, excl. developmental toxicity)	Workers & families	13,000	10,500	8,500
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€200 - 310 million	€160 - 250 million	€130 - 200 million
Avoided costs	Companies	€6 million	€5 million	€4 million
Avoided costs	Public sector	€130 million	€100 million	€90 million

Impact	Stakeholders affected	BLV options (µg/100ml)		
		Option 4: 4.5	Option 3: 15	Option 2: 20
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy for Sustainability towards a toxic-free environment		
Direct benefits – improved well-being – environmental				
Environmental releases	All	No impact/limited impact		
Direct benefits – market efficiency				
Level playing field	Companies	A harmonisation of the BLVs leads to a level playing field, as all companies across all Member States follow a more symmetric requirement. The level-playing field increases with the stringency of BLVs		
Indirect benefits				
Administrative simplification	Companies	Large companies, and to a lesser extent medium ones with facilities in different Member States, will experience administrative simplification, owing to a more harmonious set of compliance requirements. The sectors expected to benefit most are sectors 1, 2, 3, 6, and 15.		
Corporate Social Responsibility	Companies	Work with lead may be less perceived as a risky line of work associated with health issues. As a result of such an improved public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.		
No cost of setting BLV (saving for MS for developing lower national BLVs)	Public sector	Benefit (MS would expectedly not implement lower BLV)		Small benefit (some MS would consider implementing lower BLV)

Source: RPA, 2021, External Study

Diisocyanates

Table 11: Multi-criteria analysis on diisocyanates (all impacts over 40 years and additional to the baseline)

Impact	Stakeholders affected	OEL options (µg NCO/m^3)		
		Option4: 3	Option 3: 6	Option 2: 10
Direct costs – compliance				
Risk management measures and discontinuation costs (one-off and recurrent)	Companies	€830 million	€10 million	€0 million
Monitoring (sampling and analysis)	Companies	€11 000 million	€11 000 million	€4 600 million
Direct costs - administrative burdens				
Company cost of administration burden	Companies	€2 400 million	€2 400 million	€1 000 million
Direct costs – total per company				
Compliance, monitoring and administration burden	Companies	€5 900	€5 600	€2 300

Impact	Stakeholders affected	OEL options (µg NCO/m^3)		
		Option4: 3	Option 3: 6	Option 2: 10
costs per company				
Direct costs - enforcement costs				
Transposition costs	Public sector	€970 000	€970 000	€970 000
Enforcement costs	Public sector	€0	€0	€0
Monitoring costs	Public sector	€0	€0	€0
Adjudication costs	Public sector	€0	€0	€0
Indirect costs – other				
Firms exiting the market - No. of company closures	Companies	53	0	0
Employment – Jobs lost	Workers & families	100	0	0
Employment – Social cost	Workers & families	€8.5 million	0	0
International competitiveness	Companies	Several sectors are in price sensitive competitive markets with many competitors outside the EU		
Consumers	Consumers	Limited impacts expected		
Internal market Lowest to highest OEL	Companies	3 - 3	3 - 6	3 – 10
Specific MSs/regions - MSs that would have to change OELs	Public sector	All MS except SE	All MS except SE	All MS except IE, SE, PL
Regulation	Companies	Cumulative impact of many changes in regulations, implemented or awaited		
Direct benefits – improved well-being – health				
Reduced cases of ill health (asthma)	Workers & families	50	0	0
Reduced cases of ill health (irritation)	Workers & families	260	0	0
Ill health avoided, incl. intangible costs (M1 to M2)	Workers & families	€1 - 2 million	€0	€0
Direct benefits – improved well-being – safety				
Avoided costs	Companies	€0.4 million	€0	€0
Avoided costs	Public sector	€1 million	€0	€0
Social policy agenda	All	Contribution to Green Deal: Chemicals Strategy for Sustainability towards a toxic-free environment		
Direct benefits – improved well-being – environmental				
Environmental releases	All	No impact/limited impact		
Direct benefits – market efficiency				
Level playing field	Companies	A harmonisation of the OEL and STEL leads to a level playing field, as all companies across all Member States follow a more symmetric requirement. The level-playing field increases slightly with the stringency of OEL and STEL		
Indirect benefits				
Administrative simplification	Companies	Large companies, and to a lesser extent medium ones, with facilities in different Member States will experience administrative simplification, owing to a more harmonious		

Impact	Stakeholders affected	OEL options (µg NCO/m^3)		
		Option4: 3	Option 3: 6	Option 2: 10
		set of compliance requirements. The sectors expected to benefit most are C20 Chemicals, C29 Motor vehicles and C30 Transport.		
Synergy	Companies	Synergies in terms of exposure reduction to other chemical substances used in production sectors may occur. The specific substances will vary between the sectors. The level of synergy to be harnessed will also depend on the risk management measures applied in each enterprise.		
Corporate Social Responsibility	Companies	Work with diisocyanates may be perceived as a less risky line of work associated with health issues. As a result of such an improvement in the public image, companies may find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.		
Avoided cost of setting OEL	Public sector	€1 750 000	€1 750 000	€1 750 000

Source: RPA, 2021, External Study

7. 7. How do the options compare?

The main objective is to balance health considerations against economic impacts, by proposing limit values that are still economically feasible while protecting a maximum number of workers. The aim is therefore to ensure a balanced approach and to prevent industries from closures or severe disadvantages, as a result of the adoption of stringent OELs. The comparison tables used to compare the different options against the baseline scenario in terms of effectiveness, efficiency, feasibility and coherence apply the following ranking symbols: '0' – baseline, '≈' – similar to baseline, from '+' more efficient/effective/feasible or coherent than baseline to '+++' – much more efficient/effective/feasible or coherent than baseline; from '-' – less efficient/effective/feasible or coherent than baseline to '- - -' – much less efficient/effective/feasible or coherent than baseline.

Lead

Table 12: comparison of lead options

Criteria	70 µg/100ml (Baseline)	20 µg/100ml (Option 2)	15 µg/100ml (Option 3)	4.5 µg/100ml (Option 4)
Effectiveness	0	+	++	+++
Efficiency	0	-	-	---
Coherence	0	++	+++	++

The **effectiveness** is analysed from the perspective of the prevention of adverse health effects. All three policy options are more effective in terms of workers' protection than not revising the current EU-wide

biological limit value (baseline). Option 4 is the most effective policy option in terms of number of ill health cases avoided over 40 years (13 500 cases). Options 3 and 2 would also contribute to improving the protection of workers, although to a lesser extent, by preventing about 10 500 and 8 500 cases of ill health, respectively.

With regard to the **efficiency**, the options are ranked according to a comparison of the benefits arising from each policy option compared to the costs they would entail. Strictly looking at the monetised impacts, option 2 has a costs/benefits ratio close to 1 (1.2 to 1.6, depending on the methodology used to estimate the benefits for workers and their families), which means that the costs associated with this option are quite close to its benefits. The costs/benefits ratio associated with option 3 indicates that the costs are more than double the benefits (2.1 to 2.8). These two options are therefore less efficient than the baseline. By contrast, the costs/benefits ratio associated with option 4 is much higher (from 14.5 to 19.2). Thus, option 4 is therefore much less efficient than the baseline.

However, and although it is not reflected in the above table, it is worth mentioning that the costs for companies under options 2 and 3 would represent less than 1% of the annual turnover and would not lead to any discontinuation of companies, while both would ensure a much more adequate protection of workers in comparison to baseline (preventing between around 8 500 and 10 350 ill-health cases). Since the improvement of workers' protection is the main objective, all the options could be seen as more cost-effective[85] than the baseline scenario which would not bring any benefits. Furthermore, both options 2 and 3 improve the protection of workers while preventing closures and other severe disadvantages for the industries. Although the benefits are slightly higher than for options 2 and 3, the costs arising from the investments to comply with the limit value under option 4 would be substantially higher than under options 2 and 3. As a consequence, 29 companies (of which 25 are small or medium-sized enterprises) are estimated to exit the market.

Table 13: Comparison of quantified costs and benefits for options for lead (over 40 years, in € million)

	Option 2 (20 µg/100ml)	Option 3 (15 µg/100ml)	Option 4 (4.5 µg/100ml)
Costs for businesses	350	750	6 300
Benefits for businesses	4	5	6
Costs for public authorities	0.5	0.52	0.54
Benefits for public authorities	90	100	130
Health benefits for workers and families	130 - 200	160 - 250	200 - 310

Source: RPA, 2021, External Study

[85] Cost-effectiveness analyses enable to quantify the benefits that would be generated by one euro of costs imposed on society.

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 European Pillar of Social Rights and its Action Plan, the Chemicals Strategy for Sustainability 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 limit values. The lower the limit value, the more protective of workers' health.

Lowering the existing limit value at the level of each policy option would ensure a better protection of workers' health and would be in line with the Commission's commitment to reducing workers' exposure to hazardous chemicals. Therefore, these three options would ensure a greater coherence with the Charter for Fundamental Rights, the EU Pillar of Social Rights and its Action Plan and the Chemicals Strategy for Sustainability. Furthermore, lead has been identified as a substance of very high concern and placed on the candidate list for inclusion into Annex XIV to REACH since June 2018, on the grounds that it is a substance toxic to reproduction. Therefore, the lowering of the limit value at the level of all the options (except option 1) will improve the protection from a substance considered as of high concern and for which there is a need for vigilance.

In addition, option 3 is coherent with the OEL recommended by two Interest Groups within the ACSH, namely the employers' and governments' Interest Groups. The workers' Interest Group recommended an OEL at the level of option 4. Therefore, option 3 is the most coherent as it ensures the same coherence with the other EU policies as options 2 and 4 while being coherent with the opinion endorsed by a majority of members within the ACSH.

Diisocyanates

Table 14: comparison of diisocyanates options

Criteria	No EU limit values (Baseline)	10 µg/m³ (Option 2)	6 µg/m³ (Option 3)	3 µg/m³ (Option 4)
Effectiveness	0	+	+	++
Efficiency	0	-	-	---
Coherence	0	++	+++	++

With regard to the **effectiveness**, the options are analysed from the perspective of the prevention of adverse health effects. According to the available data, options 2 and 3 would not bring any additional benefits compared to the baseline. However, as explained above, the data available does not allow for a comprehensive analysis since the ill-health cases due to peak exposures could not be calculated, which results in a significant underestimation of the benefits. Therefore, the benefits of setting an OEL (and its associated STEL) at the level of one of these options would in practice be higher (the stricter the STEL the higher the avoided ill health cases) and this qualitative analysis is reflected in the above table (each policy option is higher in terms of effectiveness than the baseline). The same data limitations apply to option 4, which would in theory enable to prevent about 300 cases of asthma and irritation, while this figure should be higher in practice. The benefits related to option 4 should be higher than under options 2 and 3. The lower the limit value, the more protective of workers' health.

With regard to the **efficiency**, the options should be ranked according to a comparison of the benefits arising from each policy option compared to the costs they would entail. However, since the benefits

are underestimated due to data limitations, a purely quantitative comparison of the options does not allow to properly assess their efficiency. As explained above, the three options should produce benefits by reducing the number of ill health cases resulting from the exposure to diisocyanates. Still, it is likely that the costs would outweigh the benefits for all policy options. Considering that the costs of option 4 are not only the highest but also that this option is the only one expected to lead to company closures and job losses, it is rated as the least efficient.

Table 15: comparison of quantified costs and benefits for diisocyanates options (over 40 years, in € million)

	Option 2 10 µg NCO/m^3	Option 3 6 µg NCO/m^3	Option 4 3 µg NCO/m^3
Costs for businesses	5 600	13 410	14 230
Benefits for businesses	0	0	0.4
Costs for public authorities	0.97	0.97	0.97
Benefits for public authorities	1.75	1.75	2.75
Health benefits for workers and families	N/A	N/A	0.8 - 2.2

Source: RPA, 2021, External Study

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 European Pillar of Social Rights and its Action Plan, the Chemicals Strategy for Sustainability 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.

Setting limit values at the level of each policy option would ensure a better protection of workers' health and would be in line with the Commission's commitment to reducing workers' exposure to hazardous chemicals. Therefore, these three options would ensure a greater coherence with the Charter of Fundamental Rights, the European Pillar of Social Rights and its Action Plan and the Chemicals Strategy for Sustainability. Furthermore, and whatever the option retained, the setting of an OEL and a

STEL will be coherent with and would complement the REACH restriction introducing specific training requirements for workers using diisocyanates. Therefore, the lowering of the limit value at the level of all the options (except option 1) will improve the protection from a substance considered as of high concern and for which there is a need for vigilance.

In addition, option 3 is coherent with the OEL unanimously recommended by the ACSH in its opinion. Therefore, option 3 is the most coherent as it ensures the same coherence with the other EU policies as options 2 and 4 while being coherent with the opinion of the ACSH.

8. 8. PREFERRED OPTION

Taking into account the impacts mentioned in the previous section as well as the opinions of the ACSH, including the positions of its different interest groups, the preferred options are:

8.1 Lead

Option 3 ensures a balanced approach between adequate protection of workers at the EU level and prevention of closures and other severe disadvantages for the concerned sectors. Furthermore, it ensures coherence with key EU policies as demonstrated in the previous section.

The three Interest Groups of the ACSH, in its opinion, agree on the need to revise downwards the existing BLV as well as the OEL to better protect workers. Furthermore, they agree blood lead exposure is the best exposure metric to assess exposure. The preferred option is based on the above analysis that takes into account the RAC and ACSH opinions, together with relevant feasibility aspects.

A BLV equal to 15 µg/100ml blood, accompanied by an associated OEL equal to 0.03mg/m^3 as an 8-hour TWA is therefore the preferred option.

8.2 Diisocyanates

Option 3 ensures a balanced approach between preventing companies from closures or severe economic disadvantages while providing an adequate protection of workers at the EU level. It also ensures coherence with key EU policies. This option 3 is also coherent with the ACSH opinion, in which the three Interest Groups recommended to set an OEL of 6 µg NCO/m^3 (and an associated STEL of 12 µg NCO/m^3). An OEL equal to 6 µg/m³, accompanied with an associated STEL equal to 12 µg/m³, a dermal and respiratory sensitisation notation and a skin notation is therefore the preferred option.

However, as recommended by the ACSH, a transitional value at the level of option 2 (10 µg/m³) with an associated STEL equal to 20 µg/m³ should apply until 31 December 2028. This transitional value is considered as necessary for technical measurement feasibility reasons and to give sufficient time to the industry to implement the necessary risk management measures, in particular in downstream sectors. This should be complemented by health surveillance of workers to detect any early onset of ill-health and subsequent management of the individual worker to prevent further risks due to exposure to

diisocyanates. Collectively, this provides a high level of worker protection.8.3 Overall impact of the preferred options.

Due to a lack of data, the impacts of a combination of several limit values for diisocyanates in the form of a transitional measure and of the setting of notations could not be quantified. For that reason, the costs and benefits described below are those for the preferred option only, without any transitional measures and notations. However, it is reasonable to consider that accompanying the new EU diisocyanates OEL with transitional measures would have limited impacts on the benefits and moderate impacts on the 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.

It is difficult to predict with any certainty the expected future level of reduction in the number of cases of ill-health due to exposure to both lead and diisocyanates. However, it is reasonable to predict that following the implementation of the new and revised limit values, exposures will reduce with a consequent reduction in the number of cases of ill-health. Within the framework of the evaluations carried out under Article 17a of Directive 89/391/EEC, consideration could be given to developing a set of objective indicators specific to each substance for which a limit value has been set under CAD and CMRD.

8.3.1 Impact on workers

The preferred options considered in this impact assessment should result in benefits in terms of avoided work-related ill-health, and related monetised health benefits including avoidance of intangible costs such as the reduced quality of life, the suffering of the workers and their families, the pain, etc. For lead it is estimated that about 10 500 cases of ill-health could be prevented, and its monetised health benefit is assessed as ranging from EUR 160 million to EUR 250 million. Regarding diisocyanates, the lack of data does not allow to quantify the benefits for workers. However, it is largely agreed among relevant stakeholders, including social partners, that the setting of a STEL would result in a decrease of the number of ill-health cases.

8.3.2 Impact on business, including SMEs

As regards costs incurred for risk reduction measures, the preferred options will affect operating costs for companies which will have to adjust the working practices to comply with the new BLV and OEL for lead and OEL, STEL and notations for diisocyanates. This will consist of incremental costs of RMMs (including respiratory protective equipment (RPE)), cost of health surveillance, monitoring costs and training costs[86]. The costs to business over the next 40 years are estimated to be about EUR 750 million for companies operating with lead and EUR 13.5 billion for companies dealing with diisocyanates.

For lead, the average additional costs per company would be about EUR 30 000 over 40 years. This represents less than 1% of their turnover and should therefore not lead to any closures. Furthermore, the impacts on the expenses in research and development and on consumers should be very limited.

As for diisocyanates, each of the companies would spend on average about EUR 6 000 over 40 years. Since most of these costs are related to monitoring tasks, they spread over the reference period.

[86] Companies operating with lead will only face costs of RMMs.

Moreover, while all companies must comply with limit values, monitoring and the administrative burden of monitoring can be reduced, according to CAD, as there is no need for monitoring if companies can demonstrate adequate protection by other means. It is therefore possible that many micro-enterprises (numerous in the construction and vehicle repair sectors) will not be required to monitor their compliance. In such a case, the above indicated monitoring and administrative costs would be significantly overestimated. Regarding one-off costs, companies operating in textiles and apparel sectors would need to bear costs of EUR 4.5 billion and EUR 10.3 billion respectively. Since most of the companies operate in sectors with a high degree of competition, the impacts on consumers will be limited.

The setting of new or revised limit values should bring benefits to companies, including for diisocyanates, although these could not be quantified. For example, this would lead to cost savings related to sick leave, labour productivity and other administrative and legal costs. However, these benefits are much more limited compared to the costs arising from the setting of the limit values.

99% of the companies working with lead and diisocyanates are SMEs and, therefore, these have been the focus of this report's cost analysis.

8.3.3 Impact on competition and competitiveness

Companies that are already complying with any limit value being assessed will be impacted less in terms of their competitiveness costs following the introduction of a lower OEL, STEL or BLV as appropriate. This is particularly relevant for companies working with diisocyanates in Sweden, which has lower national OELs for a few of them.

However, whilst this might make them more cost-competitive against companies working in other Member States, most of the work done with lead and diisocyanates is carried out in fixed installations (e.g., lead battery manufacturing and recycling / primary manufacture of diisocyanates). Furthermore, the costs related to the compliance with the preferred options should not have significant impacts in terms of competition. However, companies working with lead could be less competitive compared to those producing lead-free alternative products (e.g., ceramic frit, alloys or crystalline glass).

Regarding international competitiveness, only three non-EU countries have currently a BLV for lead. However, most of them have an OEL which would correspond to a BLV of 30 µg/100ml. Therefore, the impact on companies working with lead should be moderate. When it comes to diisocyanates, the main competitors of the EU have higher limit values, which could undermine the competitiveness of companies operating in markets characterised by a high price sensitivity. However, the potential consequences are mitigated by several factors, including the limited incremental costs for companies and the non-international nature of some of the concerned markets.

8.4 Subsidiarity, proportionality and REFIT

In view of the available scientific evidence, it is necessary to review the OEL/BLV for lead and its inorganic compounds and to introduce a limit value for diisocyanates. The protection of workers' health against risks arising from exposure to these substances is already covered by EU legislation, in particular by the CAD and the CMRD, which can be amended only at EU level. The preferred options build on long and intensive discussions with all stakeholders (representatives from workers' associations, representatives from employers' associations, and representatives from governments) that helps to ensure that principles of subsidiarity and proportionality are well respected.

Updating the CAD and the CMRD 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 and thus minimising the disparities in health and safety protection levels of workers between Member States.

Although competition in the internal market not being strongly impacted by the revision of the OEL/BLV for lead and its inorganic compounds and by introducing an OEL for diisocyanates, the harmonisation of minimum requirements would contribute to a level playing field for operators in the internal market. Updating the CAD and the CMRD therefore complies with the principle of **subsidiarity**.

The **proportionality** principle is respected as the preferred option is limited to introducing an OEL and a STEL for diisocyanates by revising the annex to the CAD and by revising the limit values for lead by amending the annexes to the CMRD on the basis of the scientific and technical data available. This initiative aims to make a step forward to achieve the objectives set to improve health and safety of workers. The preferred options ensure a balanced approach, i.e., preventing companies from closures or severe economic disadvantages while providing an adequate protection of workers at the EU level. The proposal is balanced and justified in light of the accrued and longer-term benefits in terms of reducing health risks arising from workers' exposure to lead and to diisocyanates and preventing occupational ill-health. Therefore, it achieves the objectives of the Directives at the least cost.

Companies working with diisocyanates will be required to take additional actions to comply with the limit values; namely, by introducing additional Risk Management Measures, or reinforcing existing ones. Nevertheless, without limit values at EU level, disparities in the protection of workers from exposure to diisocyanates would remain. Besides, although Risk Management Measures will imply one-off costs initially, these will later be compensated by savings. For instance, investing in local exhaust ventilation systems will reduce the need to use respiratory protective equipment, which is characterised by low one-off yet high recurrent costs. When it comes to lead, the need to take new action will be limited, as no additional monitoring or administrative measures will be required.

As shown above, the estimated costs outweigh the quantified benefits for all the options. The selection of the most appropriate option per group of substances cannot be done merely on the basis of a costs/benefits ratio comparison. Due to data limitations (see section 6.1), the assessment of proportionality needs to go beyond a purely mathematical comparison of the costs and benefits. The calculations presented in the report are those which could be quantified, which was easier for the costs, as these are usually more certain and tangible than the benefits in the area of occupational safety and health. Besides, important economic benefits like those linked to reputational risks and their impacts in terms of business opportunities and the abilities to hire and retain skilled staff, could not be quantified. The limitation of benefit calculations is particularly relevant for diisocyanates. The health benefits of the STEL could not be calculated, and consequently, neither could the monetised benefits, which does not allow for a full picture. Nevertheless, the preferred option was supported by the Employers' Interest Group of the ACSH, which suggests that the costs, although high, are bearable, and they would not represent an insurmountable burden for businesses. Moreover, the costs are calculated for a total of 40 years, being therefore substantially lower when considered in annual terms. In addition, when the costs are presented in relation to companies' turnover, the preferred options both for lead and for diisocyanates represent limited costs (e.g., less than 1% of turnover for companies working with lead).

For diisocyanates, the preferred option includes a transitional measure to mitigate burdens and support compliance which has been discussed and agreed by the relevant stakeholders, including in the opinion of the ACSH. This transitional measure contributes to the proportionality of the preferred option by

ensuring a more appropriate period for businesses to adapt. While the preferred option for lead has the support of employers and national governments represented within the ACSH, the preferred option for diisocyanates is fully supported by all the interest groups within the same Committee. For diisocyanates, since there are currently no EU limit values, all Member States will be affected by the preferred option, although Member States with no limit values might be more affected than those with limit values, even if these are higher than the preferred option. For lead, some Member States might be particularly affected by the proposed options. Many of the sectors working with lead are particularly present in France, Germany, Italy, Poland and Spain. Since, in addition to this, the current limit values in those Member States are higher than the proposed option, it is likely that they be slightly more affected. Furthermore, the preferred options offer a certain flexibility to Member States. In line with Article 153(4) of the TFEU, setting OELs at 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 ones set in the annexes to the CAD and the CMRD.

Finally, regarding the **simplification** and the efficiency improvement of the existing legislation, the preferred option per group of substances eliminates the need for Member States to conduct their own scientific analysis to revise the OEL/BLV for lead or to introduce an OEL for diisocyanates. Employers also benefit from the simplification in ensuring legal compliance, particularly those operating in different Member States.

9. 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

Specific objective	Operational objective	Indicators	Monitoring arrangements/data sources for monitoring indicators
To increase the effectiveness of the CMRD and the CAD (specific objectives 1 and 2).	The reduction of occupational ill-health in the EU.	The number of cases of occupational ill-health in the EU.	The data sources for the monitoring of this indicator are: Data notified by employers to the competent national authorities as regards record keeping in accordance with national law and/or practice as resulting from occupational exposure to lead in accordance with Art. 15, 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 implementation reports on CAD and CMRD on the implementation of the directives, submitted in accordance with Art. 17a of Directive 89/391/EEC. The next

			evaluations will be for the periods 2018-2022, 2023-2027 and 2028-2032.
To achieve a more balanced and effective protection of workers across the EU against lead and diisocyanates, thereby contributing to a reduction in the burden of occupational ill-health (Specific objective 3).	The reduction of costs related to occupational ill-health for economic operators and for social security systems in the EU.	The costs related to occupational ill-health for economic operators (e.g., loss of productivity) and social security systems in the EU.	The monitoring of this indicator would require the comparison of the expected figures on the burden of occupational ill-health 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 cases of occupational ill-health. The cases of occupational ill-health accounted for should be those related to exposure to lead and diisocyanates respectively, for example, but not limited to, neurotoxicity, renal toxicity, cardiovascular effects, haematological effects and developmental toxicity in the case of lead, and occupational asthma, isocyanate sensitisation, bronchial hyperresponsiveness, and dermal occupational disease in the latter case.

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, employers must ensure that the exposure does not go above the limit values set out in the annexes to the CAD and the CMRD. 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 the two Directives.

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.

Legislative action needs to be followed up through effective implementation at the workplace. Companies have a broad range of tools, information and good practices provided by EU-OSHA in the context of a Healthy Workplaces Campaign on dangerous substances[87].

[87] The campaign pursued several objectives, including raising awareness on 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. It was carried out in 2018-2019.

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 98/24/EC and Directive 2004/37/EC. Using these reports as a basis, the Commission is required to evaluate the implementation of the directives and, to inform the European Parliament, the Council, the European Economic and Social Committee and the ACSH of the results of this evaluation and, if necessary, of any initiatives to improve the operation of the regulatory framework. The next evaluations will be for the periods 2018-2022, 2023-2027 and 2028-2032.

A key indicator to evaluate the implementation of the EU OSH Directives, and therefore the CAD and the CMRD, is the full and correct transposition by the Member States. On the one hand, Member States should notify the Commission of their transposition of EU Directives into national legislation. Where they fail to do so (non-communication), do it only partially (partial communication), and/or fail to fully transpose the Directive in an accurate and correct manner, the Commission can launch infringement procedures.

Until recently the number of binding limit values under CAD and CMRD was limited, and the above evaluations tended not to address specific chemicals and instead had a focus on the general requirements of the directives. Following successive legislative updates, there is now a significant number of limit values. Therefore, for future evaluations under Article 17a of Directive 89/391/EEC, it will be appropriate to consider developing a range of indicators to enable an assessment of the practical implementation of the substance-specific limit values to be carried out in the future, together with a continuation of the current practice of evaluating the general requirements of the directives.

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

Lead DG: Directorate-General Employment, Social Affairs and Inclusion, Unit C2 - Health and Safety at Work, EU-OSHA.

2. ORGANISATION AND TIMING

A first consultation of the Occupational Safety and Health Inter-service Steering Group (OSH ISG) on the draft Impact Assessment Report (IAR) was launched on 7 March 2022 with a meeting scheduled for 10 March 2022. 12 services (SG, SJ, BUDG, GROW, ENER, ENV, RTD, CNECT, EAC, SANTE, JUST, ESTAT) as well as EU-OSHA were consulted and invited to participate in the meeting. Most of the comments provided by the services were addressed in the revised draft IAR.

A second consultation of the ISG on the revised draft IAR was launched on 29 June 2022 with a second meeting scheduled on 6 July 2022. This second consultation was carried out with the same services as for the first consultation. DG EMPL took most of these comments into consideration in the revised version of the draft IAR.

A third consultation of the ISG, on the legislative proposal, was launched on 19 October 2022, with a meeting scheduled on 24 October 2022. DG EMPL took the comments into consideration in the revised version of the legislative proposal.

3. CONSULTATION OF THE RSB

The draft IAR for this initiative was submitted to the RSB on 14 September 2022 and the meeting with the RSB took place on 12 October 2022. Following this meeting, the RSB gave a positive opinion with reservations on 14 October 2022.

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

Table 1: RSB comments and corresponding changes

RSB opinion's comments	Corresponding changes to the draft IAR
The report should address upfront the coherence of the initiative with the REACH Restriction Regulation (Regulation (EU) 2020/1149) on diisocyanates and the need to act now given their similar objectives and the REACH Restriction Regulation's imminent entry into force in 2023.	The revised report includes a more nuanced reflection on the complementary benefits of the introduction of limit values for diisocyanates and the recently adopted restriction under REACH that requires the mandatory training of workers who may be exposed to diisocyanates. It explains that this contributes to the common aim of OSH and REACH to replace harmful chemicals by less harmful ones. This is discussed in the introduction and in section 2.2.3.2.
It should be clear about the relevance of the 2017 ex-post evaluation of the EU Occupational Safety and Health Directives including the Chemical Agents Directive and Carcinogens and Mutagens Directive.	The revised report better explains that the 2017 ex-post evaluation identified the main issues concerning the effectiveness and relevance of the CAD and the (then) CMD, but that it did not provide sufficient quantitative data (Section 2.1).
For lead, the initiative's potential contribution to	The revised report clarifies in section 4.3.5 that,

the Europe's Beating Cancer plan should be qualified based on current scientific knowledge.	although the main adverse health effects resulting from exposure to lead are on reproductive health, in rare cases it could cause cancer, which a reduction of limit values could further prevent.
The report should better present the dynamic baseline. It should be more transparent on the data used for lead regarding exposed workers and concentrations and clarify the baseline assumption that exposure concentrations in lead will remain stable. It should better describe how the main markets using the two substances will be impacted by the EU Green Deal and the consequent electrification of transport, phasing out of internal combustion engines, and overall use of greener and safer materials. For di-isocyanates the report should provide evidence supporting a growing demand. The report should explain to what extent the trend to automate industrial processes and its consequence of reducing the exposure of workers would affect the estimated future disease burden and how these trends have been factored in the dynamic baseline.	The revised report provides the sources of the data used to determine the baseline scenario (Section 5.2). It also better explains how industry developments (such as automatisation) are factored into it. The revised text also reflects on the impact of the Green Deal and the Renovation Wave.
The report should explain why the option of a phasing out of the use of lead is not considered given that lead is already banned in some Member States and alternatives exist.	Under section 5.3 (options discarded at an early stage), the revised report includes a new section (5.3.1) on the phasing out of the use of lead. It explains in detail why it was not considered a realistic policy option, as lead remains necessary for a number of critical purposes in a range of sectors including construction activities and in batteries for fossil fuel and electric vehicles. Besides, it clarifies that the CMRD does not allow for banning the use of substances and reflects on the lack of benefits that a ban on lead would have on workers who are exposed to materials for which lead was used in the past.
The report should better describe all relevant (quantified and not-quantified) costs and benefits and classify them correctly for the purpose of the One In, One Out approach. It should better explain why the benefits for the two options on di-isocyanates (including the preferred one) are not estimated. It should better justify the absence of enforcement and notification costs.	A more balanced analysis of the quantifiable and non-quantifiable costs is provided throughout the report, and the analysis of the one in one out approach is reinforced in section 6.9. It also explains the methodological limitations that do not allow for an estimation of the benefits for diisocyanates (sections 5.4.2 and 6.1) The absence of additional enforcement and notification costs is explained in sections 6.3.4 and 6.8.
The report should provide further details on the methodological limitations and uncertainties and explain how they affect the calculations.	Section 6.1 on the analytical methodology and Annex 4 in the revised report include a detailed explanation of the data limitations and of the sensitivity analysis that was carried out. Especially for diisocyanates, it explains how the lack of scientific data related to the exposure-risk relationship limits the estimation of ill-health cases, and how this affects the cost benefit calculations.
In particular, it should provide further details on	Further details on the estimation of companies

how the number of companies discontinuing activities is estimated.	discontinuing their activities are provided in section 6.3.2.
It should also consider, at least qualitatively, the transfer of jobs to companies offering alternative solutions.	The revised report reflects on this possibility yet clarifies that the transfers could not be quantified due to a lack of data (Section 6.2.2.)
The report should better justify the choice of the preferred option for both substances and significantly strengthen their proportionality assessments given that the costs outweigh the benefits for the preferred option on lead and the preferred option on di-isocyanates imposes the high costs without any quantified benefits. The report should bring together all quantified and non-quantified costs and benefits and demonstrate that the initiative meets the objectives at least cost.	The proportionality assessment has been improved, by providing a more critical approach. It considers additional actions that would potentially have to be taken by companies. It also provides a more nuanced analysis of the costs and benefits and the methodological limitations for carrying out calculations, therefore better justifying why the proportionality assessment cannot be done solely on the basis of a purely mathematical comparison.
The report should specify how and by when the initiative will be evaluated. The indicators and proposed monitoring of all specific objectives should be included in the report.	More detailed explanations of the evaluation arrangements are provided in section 9.2.

4. EVIDENCE, SOURCES AND QUALITY

Risk Assessment Committee's Opinions

The assessment of health effects of the substances subject to this proposal is based on the relevant scientific expertise from the European Chemicals Agency (ECHA)'s Committee for Risk Assessment (RAC).

RAC prepares the opinions of the (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[88].

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), Short term Occupational Exposure Limit Values (STELs) biological limit values (BLVs)/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, Council Directive 148/2009/EC, and Directive 2004/37/EC of the European Parliament and of the Council.

[88] https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment

Members of RAC are highly qualified, specialised, 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 RAC opinion on scientific evaluations for lead and diisocyanates.

RAC opinion on lead

The RAC opinion proposes a BLV of 15 µg lead/100ml blood for lead and its inorganic compounds and an OEL of 0.004 mg lead/m^3 (inhalable fraction) for lead and its inorganic compounds.

RAC opinion on diisocyanates

A threshold for bronchial hyper-responsiveness or for the development of asthma could not be observed. However, an OEL defined as an 8-hour time weighted average (TWA) exposure based on the 'NCO group' can be obtained from the exposure - excess risk relationships for hyperresponsiveness or diisocyanate asthma as derived below, based on excess risk over a working life period.

The exposure - response relationship was derived, in µg/m^3 NCO in air.

Table 2: Exposure-risk relationship

Excess risk over a working life period	Exposure - response relations in µg/m^3 NCO in air
01%	<0.025
0.5%	0.027-0.040
1%	0.055-0.070
2%	0.12-0.19
3%	0.22-0.33
4%	0.40-0.48
5%	>0.67

STEL: A 15-minutes Short Term Exposure Limit (STEL) value which is maximally a factor 2 higher than a derived OEL based on the exposure - excess risk relationship. This STEL value should not exceed 6 µg/m^3 NCO.

Notations for skin sensitisation, respiratory sensitisation, 'skin' are warranted.

Studies performed by external consultants

The Commission launched on 30 April 2020 an open call for tender[89] in order to collect information on substances with the view to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 98/24/EC (Chemical Agents)[90] and Directive 2009/148/EC (Asbestos).

[89] Call for Tender documents available at: https://etendering.ted.europa.eu/cft/cft-display.html?cftId=3559
[90] Following the adoption of CMRD the revised limit values for lead will be adopted under CMRD and not CAD.

The contract started on 28 October 2020 and lasted 10 months. The outcome of this study provides the main basis for this Impact Assessment Report and is summarised in the relevant sections of this document.

ANNEX 2: STAKEHOLDER CONSULTATION

The following consultation activities have been performed:

1. *Social Partners Consultation*: as required 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 was performed in 2020 and 2021. The first phase of social partners' consultation closed on 11 February 2021 with a confirmation of the support for the revision of the current OEL and BLV for led and to propose, for the first time, limit values for diisocyanates. The second phase consultation, focused on the envisaged content of possible proposals, closed on 30 September 2021. More information about this two-stage consultation is provided below in this Annex.
2. *Tripartite consultation (ACSH)*: the tripartite Advisory Committee on Safety and Health at Work (ACSH), composed of three full members per Member State, representing national governments, workers', and employers' representative organisations, is consulted on a regular basis. It gives, taking into account the scientific input of 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.
3. *Consultation of other stakeholders* (e.g., employers' and workers' associations specifically concerned): These consultations have been carried out in the context of the external study in order to collect detailed information on the potential impacts of establishing or revising limit values under the CAD and CMRD that is not available in published literature and internet searches.

In line with the previous amendments of the OSH Directives (namely CMD/CMRD), no *public consultation* 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 was 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 the occupational exposure limits for lead and diisocyanates.

A call for evidence was published on 21 February 2022 with a deadline of 21 March for stakeholders to provide feedback[91].

1. SOCIAL PARTNERS CONSULTATION

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

The first phase of the Social Partners consultation closed on 11 February 2021.

[91] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12745-Health-safety-at-work-protecting-workers-from-exposure-to-chemicals-lead-and-di-isocyanates-_en

The Commission consulted the Social Partners on the approach regarding the revision of a limit value for asbestos under the Asbestos at Work Directive, and the establishment or revision of binding occupational exposure limit values for lead and its compounds and diisocyanates under the Chemical Agents Directive.

Workers' organisations

Two trade unions replied to the first phase consultation, acknowledging the importance of the existing legislation. The European Trade Union Confederation (ETUC) replied on both the revision of a limit value for asbestos and the establishment or revision of binding occupational exposure limit values for lead and its compounds and diisocyanates. The European Federation of Building and Woodworkers (EFBWW) replied in detail only concerning asbestos.

Possible improvements to the EU legal framework

In response to the consultation questions *(1) Do you agree with the issues identified? (2) Are they accurately and sufficiently covered? (3) If so, do you consider that the EU should address this issue through a binding instrument?* ETUC and EFBWW are of the opinion that the EU must take new legislative initiatives that are binding to Member States. The ETUC gave detailed comments on each substance and EFBWW only on asbestos.

Lead and its compounds

ETUC, while in principle supported reducing the current limit values, expressed views that the proposed BLV in the scientific opinion adopted by the Risk Assessment Committee of the European Chemicals Agency would be discriminatory for women at the workplace[92]. Instead, they recommended the adoption of a BLV that in their opinion would guarantee equal treatment of women and men at work.

In addition, they put forward some general reflections concerning the need to improve workers' protection from exposure to reprotoxic substances and concerning the Pregnant Workers Directive 92/85/EEC[93] in this context.

Diisocyanates

ETUC supported that a binding EU OEL is needed to ensure minimum requirements for the protection of workers exposed to diisocyanates across the EU. At the same time, they expressed the view that this is the first time an EU binding OEL would be established for sensitisers with the main aim to prevent occupational asthma, and therefore this point should be discussed and agreed upon within the tripartite Advisory Committee on Safety and Health at Work (ACSH) where workers, employers and governments are represented.

Willingness to enter into negotiations

The workers' organisations believe that binding EU legislative action is needed on these issues and therefore see no need to launch a negotiation procedure pursuant Article 155 TFEU.

[92] RAC recommends to state in the Chemical Agents Directive that the exposure of fertile women to lead should be avoided or minimised in the workplace because the BLV for lead is not protective of the offspring of women of childbearing age. In ETUC's view, this is discriminatory as it could create a situation where women could not be hired in workplaces where they can be exposed to lead and its compounds.

[93] See footnote 28.

ETUC indicates, however, that it might wish to discuss complementary issues with employers and seek convergent positions on certain questions, such as the best legal instrument to protect workers from the risk of exposure to substances that are toxic and affect reproduction or the need for a new methodology to be used to limit the volume of non-threshold substances at EU level.

Employers' organisations

Three employers' organisations replied to the first phase consultation: Business Europe, SME united (European Association of Crafts and SMEs) and the European Construction Industry Federation (FIEC).

The employers' organisations supported the objective to effectively protect workers from exposure to hazardous chemicals, including by setting OELs at EU level, where appropriate. They consider this is in the interest of workers and businesses and contributes to a level playing field. However, they also raised some concerns about the approach taken when setting such values.

Possible improvements to the EU legal framework

Concerning the issues identified in the consultation paper, the employers' organisations supported the general direction of the Commission to a constant improvement of the protection of workers from exposure to carcinogens and risks arising from chemical agents at the workplace, subject to certain conditions. The process of setting limit values should be based on sound scientific evidence, technical and economic feasibility, socio-economic impact assessment, and opinion of the tripartite ACSH, as it is done currently by the Commission.

Furthermore, they stressed that a lower limit value does not always mean better protection of workers, as it depends on the feasibility to measure it and for employers to implement it.

Business Europe and SME United stressed the need to assess impact on small and medium-sized enterprises (SMEs), in particular on micro-enterprises, in terms of proportionality and feasibility of action, as well as to take account of sectoral differences.

Concerning the question on the binding instrument to be used for addressing the issues, SME United pointed out that without a deeper analysis of the impact of the new values on crafts, SMEs, and employers' obligations, they cannot assess whether such an instrument would be appropriate.

Lead and its compounds

Business Europe referred to the voluntary agreements put in place by the industry to continuously lower the exposure levels, as far as technology allows it.

They stressed that OSH legislation at EU and national level already provides a good level of protection for workers and highlighted the importance of the existing binding OEL under CAD together with other protective measures aside from the limit value.

SME United underlined that a concrete proposal on the new foreseen OEL should be submitted in order to better assess the impact on companies.

Diisocyanates

SME United is of the view that a detailed analysis of the risks for diisocyanates justifying setting a limit value is missing. However, while in principle they did not oppose the introduction of a proportionate and feasible OEL for diisocyanates in indoor workplaces, for outdoor workplaces they considered that training requirements addressing the possible risks and hazards are sufficient.

Business Europe, although agreeing with the existence of risks for workers, highlighted that the introduction of a new binding OEL would put additional obligations on employers not only to comply with the limit value, but also with the other protective measures in CAD.

They also stressed the importance of workers' protection already provided under REACH through the restriction, as well as obligations concerning the training of workers. Moreover, they noted that the Risk Assessment Committee (RAC) in the framework of the restriction mentioned that the training of workers is the most effective way of reducing exposure and impact on workers.

Business Europe expressed the need for the EU to provide more information and analysis on how effective a binding OEL would be in addition to the existing restriction under REACH.

Willingness to enter into negotiations

The employers' organisations considered that the existing preparatory procedures already involve social partners, including the ACSH consultations. Therefore, they do not want to launch a negotiation procedure pursuant Article 155 TFEU.

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 30 September 2021. This second phase consultation focused on the envisaged content of possible proposals, as required under the Treaty.

Workers' organisations

The ETUC replied to the second phase consultation. They recognised the importance of further improving the protection of workers from exposure to lead and diisocyanates and support binding action via the revision of the Directives.

Having already answered the first phase consultation, they reconfirmed their statements.

They do not see the need to enter negotiations under Article 155 TFEU to make progress on this.

Employers' organisations

Business Europe and the Shipyards' & Maritime Equipment Association of Europe (SEA Europe) replied to the second phase consultation.

Business Europe, having already answered the first phase consultation, reconfirmed their statements.

SEA Europe stated that diisocyanates are rarely used in their industry and if they could be no longer used, they would find an alternative substance.

They considered that the existing preparatory procedures already involve social partners and that the ACSH is the right place for dialogue with social partners, jointly with governments, on the next steps in the process. Therefore, they do not want to launch a negotiation procedure pursuant Article 155 TFEU.

2. CONSULTATION OF THE ACSH/WPC

The Advisory Committee on Safety and Health at Work (ACSH) adopted, on 24 November 2021, an opinion on lead for an EU binding OEL and a binding BLV under CAD (now CMRD), and an opinion on diisocyanates for a binding OEL and STEL under CAD.

Lead

Although there is consensus agreement on the need to substantially revise downwards the existing binding OEL set at 0.15mg/m^3 and BLV set at 70µg Pb/100ml blood for lead, to better protect workers' health and safety, taking into account scientific and technical developments since the current OEL and BLV were first adopted in 1982. No consensus was reached on the limit value to be proposed. Whilst the Governments' and Employers' Interest Groups supported a BLV of 15µg/100 ml, the Workers' Interest Group favoured a limit value of 4.5µg/100 ml. The differing views are presented below.

Table 1: Views of the ACSH/WPC per interest group

ACSH INTEREST GROUP	OEL LIMIT VALUES				BIOLOGICAL LIMIT VALUE	Transitional measures
	8 hours		Short-term			
	mg/m^3	ppm	mg/m^3	ppm		
GIG	0.03[1)]		-	-	15 µg Pb/100ml blood [1)]	
EIG	0.05[1)]		-	-	15 µg Pb/100ml blood	Until 5 years after entry into force a BLV of 20 µg Pb/100ml applies. Sites engaged in the processing of lead ores and concentrates ('Primary Lead Producers') receive an extra transition time of 3 years to reach the BLV of 15 µg Pb/100ml blood
WIG	0.004		-	-	4.5 µg Pb/100ml blood	

1) Exposure of fertile women to lead should be avoided or minimised in the workplace because the BLV for lead does not protect offspring of women of childbearing age. The blood lead level in women of childbearing age should not exceed the (95 percentile) reference values of the general population not occupationally exposed to lead in the respective EU country. Higher blood lead levels are an indicator of potentially exceeded occupational exposure and should be followed up by an occupational hygiene expert. When national reference levels are not available, blood lead levels in women of childbearing age should not exceed the Biological Guidance Value (BGV) of 45 µg/L, the maximal European reference value.

Diisocyanates

There is consensus agreement on the need to adopt a binding OEL and STEL under CAD to be set at:

Table 2: Consensus of the ACSH/WPC on diisocyanates

NAME OF THE CHEMICAL AGENT	OEL LIMIT VALUES				Notation	Transitional measures
	8 hours		Short-term			
	µg NCO/m^3	ppm	µg NCO/m^3	ppm		
Diisocyanates, O = C=N-R-N = C=O, with R an aliphatic or aromatic hydrocarbon unit of unspecified length	6		12	-	Dermal and respiratory sensitization, Skin	20 µg NCO /m^3 as STEL and 10 µg NCO /m^3 as TWA till 2029

3. CONSULTATION OF OTHER STAKEHOLDERS

In the context of the external study, consultation activities have been carried out to collect detailed information on the potential impacts of modifications to the CAD and CMRD that is not available in published literature and internet searches. Although some information on OELs, STELs and BLVs is available, limited information is available on the specific concrete risk management measures already in place, as well as those that would need to be implemented, should the proposed new and revised limits be introduced.

The consultation aimed at gathering primarily factual information (e.g., on the existing Risk Management Measures), which was then used to develop an accurate baseline scenario and outline preliminary stakeholder views on the possible limit values and the consequences they could have for companies, for example, on the initial investment needed and the recurrent costs that could be expected. The information sought via consultation covered multiple factors, such as sizes of companies, sectors and processes that would be affected, number of workers exposed, annual company turnover, the specific substances related to their activities and the current air concentrations of substances concerned (both 8-hour time weighted averages (8-h TWA) and 15-minutes reference periods), results of biological monitoring, risk management measures currently in place, as well as risk management measures that would need to be implemented should the OEL, and BLV for lead be revised and an OEL and STEL for diisocyanates be introduced, together with associated costs. The consultation also sought companies' views on hypothetical future limit values, to obtain an anticipated estimate of the cost range for any additional Risk Management Measures that would be necessary. Consequently, input from the industry strongly fed into the cost calculations.

The consultation carried out for the purposes of the study consisted of the following main activities:

- Questionnaires;
- Email requests (possibly in combination with questionnaires);
- Telephone interviews;
- Site visits.

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. Stakeholders were also able to download a PDF version of the questionnaire via the website if they preferred (so that it could be shared among several colleagues, for example).

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

Specific values were established for the purposes of the stakeholder consultation. The specific values function as reference points to the consultees, who may otherwise have found it impossible to provide data on the costs of the measures being considered.

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 values for lead be lowered, and limit values for diisocyanates be introduced and any other impacts that could result from these new and revised limit values at EU level.

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 below 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 the existing limits for lead were lowered, and limits introduced for the first time for diisocyanates and other potential ramifications for the company.

3.3. Email requests

As supplement to the interviews, various information was obtained 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 CAD and CMRD were also asked whether they would be willing to host a site visit, real or virtual. 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 obtain a detailed operational understanding of the risk management measures that have already been implemented to protect workers from exposure to lead and disocyanates, as well as of the risk management measures that would be needed, and their associated costs should the limits be reduced.

Detailed notes from the 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.

Due to the COVID-19 restrictions in place for the duration of the study, fewer physical site visits took place than for previous studies. Companies were furthermore reluctant to hold virtual site visits due to the confidential nature of the information to be shared.

3.5. 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 3: 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 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: External study (RPA 2021)

4. CALL FOR EVIDENCE

A call for evidence was published on 21 February 2022 with the deadline for comments running until 21 March 2022. During this period, 38 formal replies were received from a variety of stakeholders and also from an individual citizen. From the 38 replies, 1 was disregarded as it did not relate to lead and diisocyanates. The replies are divided per type of organisation as follows:

Type of organisation	No. of replies
Company/Business organisation	13
Business Association	12
Trade Union	5
NGO (Non-governmental organisation)	2
Academic/Research Institution	1
EU Citizen	1
Other	3
Grand Total	37

In terms of the size of companies, 15 replies arrived from large companies (250 or more employees), 9 from small and medium companies (less than 250 employees) and 12 from micro companies (less than 10 employees) together with 1 EU citizen.

The geographical spread and associated number of replies was PL 9, DE 8, BE 5, SE 4, CZ 3, FR 2 AT 1, FI 1, RO 1 and from outside EU 3 replies from the UK.

Feedback from trade unions reflects in principle the same concerns and opinions of the workers' organisations as in their reply to the EU social partners' consultation. Trade unions in general call for a lowering of the limit values for lead and the introduction of limit values for diisocyanates. For lead, they expressed concern about the need to protect the unborn foetus and the need to ensure equality of treatment of men and women at work.

Companies' and business organisations' feedback is in line with the position of the employers' organisations given during the EU social partners' consultation. For lead, they recognise that both the OEL and BLV are in need of revision. However, the revised limit values need to be proportionate to the risk and consider the socio-economic impact and the level of investment required. Given the capital investment required, a significant transition period may be necessary. For diisocyanates, they generally welcome this initiative. There are some varying replies as regards the effectiveness of the REACH restriction requiring workers to be trained before using diisocyanates. Some replies considered that the OSH and REACH initiatives collectively provide a framework that fully protects workers, whilst some others were critical of the REACH restriction and preferred regulation only under OSH.

The reply from academia supports the plans to set EU limit values for diisocyanates to prevent occupational asthma.

The reply from the citizen focused on the use of lead in explosives and the need to lower the limit values whilst ensuring the correct functionality of explosives and not to create regrettable substitution.

ANNEX 3: WHO IS AFFECTED AND HOW?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

1.1. Consumers/Workers

- Due to the high degree of competition in the affected sectors, there is a very limited risk of costs arising from working under new or stricter limit values being passed on to citizens/consumers as increased prices;

- Workers will 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., revised OEL and BLV for lead and the newly established OEL and STEL for diisocyanates).

1.2. Businesses

Employers:

- Must adjust the working practices to comply with the new and revised limit values, in particular reinforcing existing risk management measures.
- May find it easier to recruit and retain staff, reducing the cost of recruitment and increasing the productivity of workers.

1.3. Administrations

Member States must transpose the amended Directives (CAD & CMRD) into national legislation.

2. SUMMARY OF COSTS AND BENEFITS FOR LEAD

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Savings for companies	€5 million	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.
Savings for public sector	€100 million	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.
Savings for workers & families	€160 – 250 million	More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding ill-health (including their offspring), 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).

II. Overview of costs – Preferred option					
		Businesses		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**
	Compliance costs	€565 million	€180 million	€500,000	€0
	Monitoring costs	€0	€0	€0	€0
	Administrative costs	€0	€0	€0	€0
Costs related to the 'one in, one out' approach					
Total	Direct adjustment costs	€565 million	€180 million		
	Indirect adjustment costs	€0	€0		
	Administrative costs (for offsetting)	€0	€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).

3. RELEVANT SUSTAINABLE DEVELOPMENT GOALS FOR LEAD

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG no. 3 – Good health and well-being. Ensure healthy lives and promote well-being for all at all ages	The initiative will contribute to substantially increasing the health of the workforce in the European Union through the prevention of ill-health due to exposure to lead.	The initiative will avoid 13 379 cases of ill-health (including developmental toxicity) to occur in the next 40 years from exposure to lead.
SDG no. 8 - Decent work and economic growth. Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all	Through the lowering of the BLV and OEL the initiative will contribute directly to a decent work environment.	The benefits of healthier staff and better working conditions will contribute to an easier recruitment and retention of staff. Workers' productivity will likely also increase, as a result of lower absenteeism.
SDG no. 9 - Industry, innovation and infrastructure. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	The initiative will impact positively the development of new technology as a consequence of the need to implement more efficient risk management measures to comply with the stricter BLV and OEL.	
SDG no. 12 - Responsible production and consumption. Ensure sustainable consumption and production patterns	A reduction in exposure to lead is expected as a result of risk management measures put in place to comply with a stricter BLV and OEL. Thus, the initiative would have a limited positive impact, namely on the environmentally sound management of chemicals and all wastes throughout their life cycle.	

4. SUMMARY OF COSTS AND BENEFITS FOR DIISOCYANATES

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Savings for companies	€0	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.

Savings for public sector	€0	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.
Savings for workers & families	€0	More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding ill-health, 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).

II. Overview of costs – Preferred option					
		Businesses		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**
	Compliance costs	€14.8 million	-€4.4 million	€970,000	€0
	Monitoring costs	€0	€11 000 million	€0	€0
	Administrative costs	€0	€2 400 million	€0	€0
Costs related to the 'one in, one out' approach					
Total	Direct adjustment costs	€14.8 million	€11 000 million		
	Indirect adjustment costs	€0	€0		
	Administrative costs (for offsetting)[94]	€0	€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).

5. RELEVANT SUSTAINABLE DEVELOPMENT GOALS FOR DIISOCYANATES

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG no. 3 – Good health and well-being. Ensure healthy lives and promote well-being for all at all	The initiative will contribute to substantially increasing the health of the workforce in the European Union through the prevention of	The initiative will avoid 106 910 cases of asthma and 10 099 cases of irritation to occur in the next 40 years

[94] The above €2.4bn administrative costs are covered by one of the exemptions to the offsetting obligation in the context of the 'one in, one out' approach in line with Better Regulation Tool #58 'EU Standard Cost Model' (namely, inspections on behalf of public authorities).

ages	asthma and irritation due to exposure to diisocyanates.	from exposure to diisocyanates.
SDG no. 8 - Decent work and economic growth. Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all	Through the introduction of the OEL and STEL the initiative will contribute directly to a decent work environment.	The benefits of healthier staff and better working conditions will contribute to an easier recruitment and retention of staff. Workers' productivity will likely also increase, as a result of lower absenteeism.
SDG no. 9 - Industry, innovation and infrastructure. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	The initiative will impact positively the development of new technology as a consequence of the need to implement more efficient risk management measures to comply with the OEL and the STEL.	
SDG no. 12 - Responsible production and consumption. Ensure sustainable consumption and production patterns	A reduction in exposure to diisocyanates is expected as a result of risk management measures put in place to comply with the OEL and the STEL. Thus, the initiative would have a limited positive impact, namely on the environmentally sound management of chemicals and all wastes throughout their life cycle.	

ANNEX 4: ANALYTICAL METHODS

The calculations of ill-health cases, and the cost-related calculations are based on a 40-year reference period, to take into account the total risk over the working life. This allows to present a long-term view, instead of considering only the risks that might manifest at the early stages of exposure.

4.1 Estimation and Monetisation of the Health Impacts

4.1.1 Health impacts

The revision of the current BLV and OEL for lead and new OEL and STEL for diisocyanates is expected to result in a reduction of exposure to both substances. The extent of such reduction depends on the current levels of exposure, as well as on projected future levels of exposure in the absence of the proposed measures, i.e., the baseline scenario.

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

- ERRs and DRRs for the relevant health effects;
- numbers of workers exposed;
- exposure concentrations (diisocyanates) or blood lead levels (lead); and
- past and future trends in the exposed workforce and exposure concentrations.

This methodology section deals with the principles of this estimation procedure.

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.

Data on exposed workforce are available from national databases in a number of Member States. The data in general include exposed workforce from activities subject to notification. This data was then extrapolated to the EU27 on a per capita basis.

4.1.2 Monetisation of the health impacts

Specific guidance is provided in the Better Regulation (BR) Toolbox for health impacts (BR Tool #32). This is summarised in the table below.

Table 1: Better Regulation Toolbox on health 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: External study. RPA (2021) (*Source: Better Regulation (BR) Toolbox – Tool health impacts (BR Tool #32))*

- **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. Other direct costs may be incurred by the patients (say, the cost of transport to attend appointments) but also by their families/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[95] 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.

4.1.3 Benefits model

4.1.3.1 Introduction

[95] From a welfare economic perspective.

The key health endpoints 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 2: Key health endpoints

Substance	Carcinogenic endpoints	Non-carcinogenic endpoints
Diisocyanates	-	Asthma Irritation
Lead and its compounds	Central Nervous System (CNS Cancer)	Neuropathy Anaemia Chronic kidney disease stage 1 Elevated blood pressure Male fertility Pre-eclampsia Developmental toxicity

Source: External Study RPA (2021)

The key model inputs are used to estimate the number of cases of ill health over the relevant period. The exposed workforce is divided into several bands which are characterised by variations in some of these inputs and for which the incidence of ill health is estimated separately and subsequently aggregated into totals for each substance.

Table 3: Key model inputs

Parameter	Explanation
Exposure-risk/dose-response relationship	Exposure-Risk Relationship (ERR) for cancer effects or Dose-Response Relationship (DRR) for non-cancer effects.
Exposed workforce	Number of workers exposed.
Exposure concentration	For OELs: 8-hr TWA (time-weighted average) that the workers are exposed to (real concentration, i.e., if personal protective equipment (PPE) is currently worn, the measured concentrations are adjusted to take into account PPE where possible). For STELs: 15-min peak exposure (real concentration after taking into account PPE). For BLVs: the concentration of the relevant substance or metabolite in the relevant biological media such as blood or urine.
Trends	Past and future trends in numbers of workers exposed and/or exposure concentrations.

Source: External Study RPA (2021)

In addition to the key inputs set out above, the model relies on a range of assumptions that determine when the relevant effect occurs or is diagnosed, the nature and severity of its effects, and how long these effects (or their consequences) last. These assumptions differ by substance and health outcome. Some of these assumptions are a simplification of complex real-life scenarios or best estimates (where authoritative evidence could not be identified from available literature).

The key areas in which assumptions had to be made to enable the model to estimate and monetise the incidence of ill-health over the relevant assessment period are set out below.

Table 4: Further 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 does not increase further).
Lat	The latency with which the effect is demonstrated.
Dist	The distribution of cases over the period between MinEx and the MaxEx: the default assumption is a linear accumulation of risk over the relevant period.
The effects of the disease	
Mortality	Mortality rate as a result of the relevant condition.
Severity	The typical severity (mild to severe) of the relevant outcome – where a range of severities is expected, a weighted average has been estimated.
Value of a case	Monetary value of a case taking into account the direct, indirect, and intangible costs estimated relying either on a) Willingness to Pay (WTP) for a case of mortality or morbidity or b) monetised Disability Adjusted Life Years (DALYs).

Source: External Study RPA (2021)

The model provides an 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 assessment period;
- the Present Value (PV) of the direct, indirect, and intangible costs of these cases.

4.1.4 Key model inputs

4.1.4.1 Rx: estimate of the risk or fraction of workers affected

The risk of developing the relevant effect is estimated by combining exposure concentrations with:

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 of exposure. The DRR is typically defined for the

health endpoint as it occurred in the underlying study and does not provide an indication for progression of disease severity. This is taken into account in the course of monetisation of the cases estimated by the model.

For cancer: Exposure-Risk Relationship (ERR), i.e., excess risk of developing cancer due to lifetime occupational exposure to a substance (40 years).

4.1.4.2 ExW: exposed workforce

The sources of data and assumptions used to estimate the numbers of workers exposed to the relevant substance are detailed in the substance-specific reports, together with the expected future trends.

As a default value, it is assumed that there is a staff 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. However, it is common that, e.g., construction workers would continue to work within construction for a major part of their work life, but it is uncertain to what extent they would continue with a job function with a specific exposure situation.

We consider, in accordance with the assumptions in the previous RPA & COWI studies, that a ratio of 5% is deemed appropriate to account for the fact that some workers may continue to work in the same sector and continue to be exposed to the same substances.

4.1.4.3 Cx: Exposure concentrations

For each substance, one or more exposure scenarios have been modelled based on data sourced from literature and consultation – these scenarios are used for the estimation of the costs and benefits (cost savings from reduced ill-health) of the OEL and BLV policy options.

The number of workers exposed at levels of relevance for the assessment of establishing an OEL is derived from consultation with relevant companies and industry associations, databases, literature, workers' associations and other sources. For each of the relevant sectors, distributions of workers over exposure levels were established. In general, it is assumed that the exposure concentrations are lognormal distributed, and exposure data collected for this study are fitted to a lognormal distribution for which the key parameters such as the 50th, 75th, 90th and 95th percentiles are estimated (please note that these parameters may differ between substances).

4.1.5 **Key assumptions**

4.1.5.1 Onset of the disease

MinEx & MaxEx - The minimum and maximum exposure duration required to develop the endpoint

No cases arise until the minimum exposure duration required to develop the endpoint (MinEx) has been reached. No further increase in risk is assumed to arise with increasing exposure time after the expiration of the MaxEx.

The basis for estimation of MinEx and MaxEx for each of the substances is described in the substance-specific reports. The default MinEx is two years for cancer, a standard assumption for a chronic condition. However, for practical reasons, the risk of developing cancer is assumed by the model to start in the first year of exposure and accumulate in a linear fashion up to a full risk estimated on the basis of the ERR after 40 years of exposure – this may lead to a slight overestimation of the risk. The minimum

exposure (MinEx) periods in the table below have been derived using a precautionary approach that maximises worker protection.

The MaxEx reflects the time needed to reach the maximum risk estimated on the basis of the ERR/DRR and exposure concentration or biomonitoring. MaxEx is either based on the situation in the key studies used to derive the DRR (if workers were exposed for ten years in that study, it has been proposed that MaxEx is ten years because this was the exposure time leading to the effect size used for the DRR) or converted to a full working life (40 years).

Table 5: Minimum and maximum exposure duration to develop a condition (MinEx and MaxEx)

Substance	Endpoint (ERR or DRR)	MinEx (years)	MaxEx (years)
Diisocyanates	Asthma	1 day (0 years)	40
	Irritation	1 day (0 years)	1 day (0 years)
Lead and its compounds	CNS cancer	2 (for practical reasons the model assumes 0)	40
	Neuropathy	1 day (0 years)	7
	Anaemia	1 day (0 years)	10
	Chronic kidney disease	1 day (0 years)	5
	Elevated BP	1 day (0 years)	10
	Male fertility	1 day (0 years)	3
	Pre-eclampsia	1 day (0 years)	No information available – assumed to be 1 in order to be conservative
	Developmental toxicity	1 day (0 years)	No information available – assumed to be 1 in order to be conservative

Source: External Study RPA (2021)

4.1.5.2 The distribution of cases over time

Valuing the cost of occupational illness involves applying discounted costs to future cases which requires that the estimated cases over the period between MinEx and MaxEx are assigned to specific years.

The distribution of cases between start of exposure and the MaxEx is modelled based on the assumption of a linear accumulation of risk over time with the maximum risk being achieved at MaxEx. The risk in a given year thus equals Risk=Risk at MaxEx/(MaxEx-MinEx).

For reasons of simplicity, the following approach is used to distribute the total risk (i.e. not incidence since incidence is delayed due to latency) over the 40 period assessed in this study. As noted above, although in theory no risk arises until the MinEx of two years has expired, for practical reasons, the models used for this study adopt a conservative approach and assume that risk arises from Year 1. It is assumed that the distribution is linear, i.e. 1/40 of the excess risk arises in Year 1 and 100% of the excess risk predicted for a specific exposure concentration arises by Year 40.

4.1.5.3 *Latency*

The estimated risk is combined with latency to estimate the specific year of diagnosis of a case.

For non-cancer endpoints the estimated latency period for the non-cancer endpoints in this study is 0 years. There is limited evidence for latency of the relevant non-cancer conditions and these are study team assumptions derived for the purposes of the modelling for this study.

For cancer endpoints by way of simplification, default latency values are used unless more detailed estimates exist for the specific substance. 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.

4.1.6 The effects of the disease

4.1.6.1 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 0% with the exception of lead where 80% for CNS cancer and 1.5% for pre-eclampsia are used.

4.1.6.2 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 6: Treatment periods

Substance	Endpoint	Treatment period (years)
Diisocyanates	Asthma	1
	Irritation	1
Asbestos	Lung cancer and mesothelioma	5
Lead and its compounds	CNS Cancer	5
	Neuropathy	20

Substance	Endpoint	Treatment period (years)
	Anaemia	1
	Chronic kidney disease stage 1	20
	Elevated blood pressure	20
	Male fertility	5
	Pre-eclampsia	1
	Developmental toxicity	1

Source: External Study RPA (2021)

4.1.6.3 Monetary value of the relevant endpoint

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

Table 7: Benefits framework

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[96]	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	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	

[96] 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 cost savings (benefits) as generated by this study.

Category	Cost	Notes
	Approach 2 Mortality DALY:	
	Approach 2 Morbidity DALY:	

Source: External Study RPA (2021)

All of the costs in the table above have been quantified to ensure that the study can estimate the impacts on individual stakeholder groups. The approach to the derivation of the costs for each of the cost categories above is set out below.

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

Method 1: Application of WTP values to each case (differentiating between mortality and morbidity); and

Method 2: Use of DALYs (Disability adjusted life year) and their monetisation.

The only difference between Method 1 and Method 2 is the way in which avoided cases of ill health are monetised. Both methods monetise the same number of avoided cases of ill health.

4.1.7 Benefits assessment

4.1.7.1 benefits to workers and 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 of work).

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.

4.1.7.2 Benefits to employers

Introducing limit values has obvious cost savings for workers, namely in terms of their health but also, indirectly, on their earnings. Employers will also accrue cost savings from their employees being less at risk of occupational illness. Such cost savings include:

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

4.1.7.3 Benefits 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 treatment as well as days off due to illness. Luengo-Fernandez et al. (2013)[97] developed an 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 EUR 5 047 is given for productivity losses and EUR 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. As discussed above, it is not clear whether the figures adopted in the external study to reflect the intangible or human costs of cancer mortality and morbidity 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.

4.1.7.4 Benefits for the public sector - cost of healthcare

The unit costs used for monetisation are summarised below. Please note that some of the costs set out in the preceding sections have been rounded. For the purposes of calculating the healthcare costs of illness, we will make use of the average 'all cancers' figure of EUR 6 047 per case of cancer (updated to 2021 as approximately EUR 7 200).

Table 8: Unit costs used for monetisation

Endpoint	Direct costs			Indirect costs		Intangible costs		
	Healthcare	Informal care	Costs for employers	Mortality – productivity loss	Morbidity – lost working days	Approach 1 WTP: Mortality	Approach 1 WTP: Morbidity	Approach 2 DALY: Morbidity
Asthma	€30,000	€0	€12 000	€0	€31 106	€0	€32 000	Value of a DALY €100,000
Irritation	€500	€0	€500	€0	€500	€0	€500	Value of a DALY €100,00

[97] See https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70442-X/fulltext

Endpoint	Direct costs			Indirect costs		Intangible costs		
	Healthcare	Informal care	Costs for employers	Mortality – productivity loss	Morbidity – lost working days	Approach 1 WTP: Mortality	Approach 1 WTP: Morbidity	Approach 2 DALY: Morbidity
								0
CNS Cancer	€7 200	€3 000	€12 900	€5 000	€5 416	€4 710 000	€455 000	Value of a DALY €100,000
Neuropathy	€1 000	€0	€0	€0	€29 778	€4 710 000	€107 201	Value of a DALY €100,000
Anaemia	€4 000	€0	€2 400	€0	€1 500	€4 710 000	€5 000	Value of a DALY €100,000
Chronic kidney disease stage 1	€1 400	€0	€1 800	€0	€29 778	€4 710 000	€1 000	Value of a DALY €100,000
Elevated blood pressure	€800	€0	€1 800	€0	€148 890	€4 710 000	€5 000	Value of a DALY €100,000
Male fertility	€1 400	€0	€0	€0	€0	€4 710 000	€5 416	Value of a DALY €100,000
Pre-eclampsia	€7 600	€900	€5 500	€5 000	€100	€4 710 000	€5 000	Value of a DALY €100,000
Developmental toxicity	€0	€0	€0	€0	€20 300	€0	€9 600 (per lost IQ)	€0

Source: External Study RPA (2021)

4.2 COST MODEL

4.2.1 The Cost Model for Estimating Compliance Costs

The cost framework used for the assessment focuses on the general features of the model for estimating compliance costs for companies for diisocyanates and lead.

Taking into account the direct and indirect behavioural changes as well as potential ultimate impacts, the most relevant impacts were selected on the basis of the following factors:

- The relevance of the impact within the intervention logic;
- the absolute magnitude of the expected impacts;
- the relative size of expected impacts for specific stakeholders (such as impacts which may be small in absolute terms but may be particularly significant to specific types of companies, regions, sectors, etc.); and
- the importance of the impacts for the Commission's horizontal objectives and policies.

The table below summarises the impact categories that could be significant and that are thus assessed in this report.

Table 9: Assessment of the most significant economic impact categories

Impact category	Key impacts
Operating costs and conduct of business	• Will it impose additional adjustment, compliance or transaction costs on businesses? • Does it impact on the investment cycle? • Will it entail the withdrawal of certain products from the market? • Will it lead to new or the closing down of businesses? • Are some products or businesses treated differently from others in a comparable situation?
Administrative burdens on businesses	• Does it affect the nature of information obligations placed on businesses?
Trade and investment flows	• How will the option affect exports and imports out of and into the EU? Will imported products be treated differently to domestic goods? • How will investment flows be affected and the trade in services? • Will the option affect regulatory convergence with third countries? Have international standards and common regulatory approaches been considered?
Public authorities	• Does the option have budgetary consequences for public authorities at different levels of government (EU own resources, national, regional, local), both immediately and in the long run? • Does it bring additional governmental administrative burden? • Does the option require the creation of new or restructuring of existing public authorities?
Consumers and households	• Does the option affect the prices consumers pay for goods and services? • Does it have an impact on the quality or safety of the goods/services consumers receive? • Does it affect consumer choice, trust or protection?

Impact category	Key impacts
	• Does it have an impact on the availability or sustainability of consumer goods and services?
Specific regions or sectors	• Does the option have significant effects on certain sectors? • Will it have a specific impact on certain regions, for instance in terms of jobs created or lost? • Is there a single Member State, region or sector which is disproportionately affected (so-called "outlier" impact)?

Source: Better Regulation (BR) Toolbox (BR Tool #19)

4.2.1 Key features of the compliance cost model

4.2.1.1 Key factors influencing costs

The key impact are the compliance costs for industry. These are estimated by means of a compliance cost model. This considers the Risk Management Measures (RMMs) currently in place and estimates the additional RMMs needed for reducing the air exposure levels from the actual levels to the target level.

The model calculates the costs for a group of similar companies incurred in reducing exposure to a target limit value based on an assumed sequence of RMM implementation which is determined by suitability, effectiveness, and cost.

The output is the cost of implementing the OEL/BLV split by:

- Sector;
- company size: small, medium and large; and
- capital expenditure (one-off) and operating expenditure (recurrent).

The model estimated the costs of compliance with the different target OELs for diisocyanates and lead. The key model inputs and assumptions are:

- OEL/BLV options;
- assumptions about how compliance with the OEL/BLV is determined;
- number of small, medium and large enterprises at each of the current exposure concentrations;
- estimated average number of exposed workers and workstations using the substance in a company;
- discount rates;
- Current RMMs;
- RMM effectiveness;
- cost of RMMs (one-off and recurring) as well as their average lifespan; and
- suitability of specific RMM types for each of the sector.

4.2.1.2 Discount rates

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

4.2.1.3 Current RMMs

The breakdown of RMMs currently used by the relevant companies, differentiated by enterprise size and sector, was estimated for each substance. The data sources and methods of estimation are described in each of the substance-specific reports.

The following types of RMM are considered:

- 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 each type of RMM, several levels that companies can achieve have been defined. These levels are summarised below.

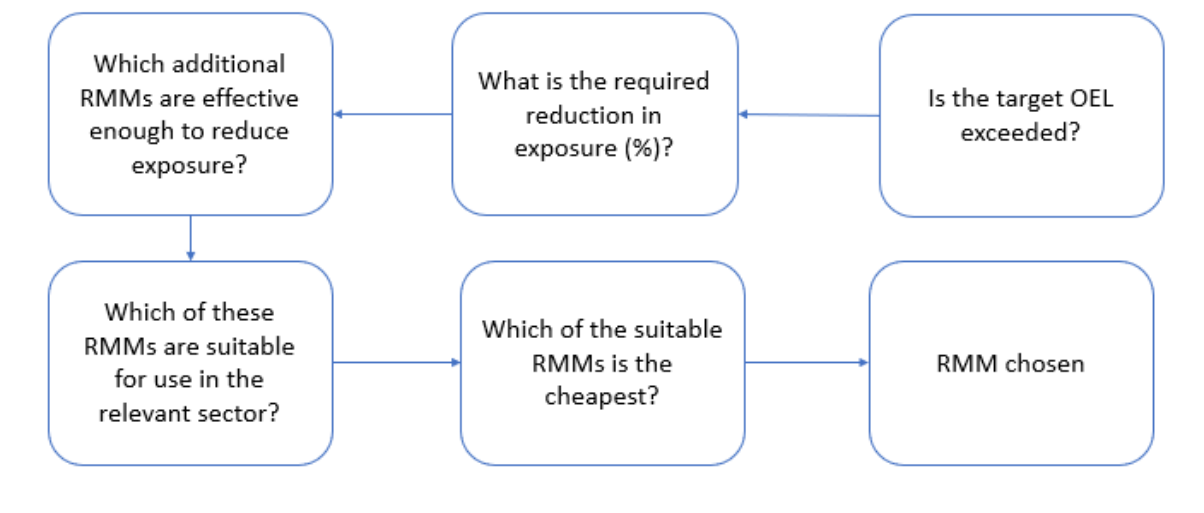
The model is a simplification of reality and focuses on the primary RMM currently used to control exposure. It is recognised that in reality a combination of RMMs may be used by a single company to control exposure. A further simplification is that current RMMs are defined at sectoral rather than company level – all companies in a certain sector are thus assumed to have the same RMMs in place. Again, it is recognised that this is a simplification which may not be the case in real life.

4.2.1.4 How does the estimation model work?

The assumptions on the effectiveness and suitability of individual RMMs are used to determine whether a specific RMM is suitable to reduce exposure in a specific sector by the required degree. If several RMMs are suitable and effective enough, the cheapest one is selected. RMMs that companies already have in place are taken into account and a more effective RMM is chosen.

The logic process underpinning each company level decision is illustrated in the figure below.

Figure 1 Decision making process in the cost estimation model for diisocyanates and lead (estimated for each company)



Source: External Study RPA (2021)

The total cost of reduction is then calculated as a sum of all company-level decisions.

4.2.1.5 Discontinuations in the cost model

Where the RMMs considered in the cost model are not sufficiently effective to achieve the reduction in exposure levels required to comply with an OEL/STEL/BLV option, it is expected that the company in question would have to substitute the substance, or where this is not possible, discontinue the activities that involve exposure to the substance. In a worst-case scenario, the company may have to shut down.

The discontinuation of activities by companies is calculated based on the cost of the RMMs in relation the turnover and profit margin for an individual enterprise. The discontinuation cost is taken as the loss of profit taken over 20 years and the average profit is assumed to be 10% of turnover. A prediction of whether a company would have to discontinue its operations is one of the outcomes considered in the cost model, usually the one associated with the highest cost. Therefore, generally,

the model only chooses discontinuation if no RMM (or combination of RMMs) can achieve the required reduction in exposure. The model assumes that small and medium enterprises discontinuing the operations that involve exposure to the relevant substance would result in the entire company going out of business. The logic behind this is that small and medium organisations are more likely to experience closure if their sole or main operation becomes unfeasible. In contrast, large companies are more likely to discontinue divisions, lines or specific operations which would not result in the full closure of the business but the discontinuation of the line/process using the relevant substance.

If the sector is entirely based on the substance, it is possible that 100% of large companies would also be forced to close. In the lead report, the business of the companies in the main sectors (primary and secondary lead producers, lead acid battery manufacturers, lead article manufacture) is entirely based on lead, meaning that, if they could not meet the relevant BLV/OEL option, the relevant companies would shut down. For other sectors with exposure to lead, discontinuation would only apply to certain activities or divisions of the company. For example, a glass manufacturer may discontinue production of lead crystal glass tableware but continue to produce tableware of lead-free glass. In such cases, only the lost profit of the division or activity including lead exposure should be accounted for in the calculation of discontinuation costs. However, such granular data have not been available, and the discontinuation of certain divisions or activities is therefore not accounted for. This leads to an overestimation of the discontinuation costs in the case of lead.

4.2.1.6 Exposure sampling and analysis

The costs of monitoring air concentrations (sampling and analysis) are estimated separately to the core model.

4.3 Methodological limitations

The calculations in the report are subject to certain methodological limitations. Regarding lead, exposure concentrations, the number of workers and their turnover are key determinants of the costs and benefits. A sensitivity analysis was performed to simulate two scenarios for each of those three factors, one with an increase and one with a decrease. In the case of concentration levels, these were calculated with a 5% increase and a 5% decrease, while for the number of exposed workers each scenario corresponded to a 50% increase or decrease. To include the turnover in the sensitivity analysis, a doubling of the annual rate from 5% to 10%, resulting in a turnover of workers of 100% in 10 years was used for the increased scenario, while for the decreased scenario a halving of the annual rate (from 5% to 2.5%, resulting in a 100% turnover of workers over 40 years), was used. In general, costs-benefit ratios did not change significantly for the two first. Only in the case of worker turnover (as it affects only the calculation of the benefits) did the ratio improve (higher turnover) or decreased (lower turnover) more significantly. Besides, a discount rate was factored in the calculations; namely, a declining discount rate of 4% over the first 20 years and of 3% in the last 20 years. The results showed that costs and benefits are mainly equally distributed over time.

For diisocyanates, the main methodological limitation impacting the robustness of projections is the lack of scientific data to assess the health benefits of the different options. Whilst peak exposures are particularly important in the development of occupational asthma, related ill-health cases could not be modelled due to a lack of data on short-term exposures (see section 5.4.2). This results in an underestimation of the costs and a significant underestimation of the benefits (asthma accounts for

more than 90% of the future disease burden) and the impossibility to calculate the impact of the different STEL options in terms of ill-health cases avoided. Consequently, it does not allow for a purely quantitative comparison of the options.

Although no sensitivity analysis could be performed to factor in the uncertainties related to short-term exposure, a sensitivity analysis was indeed performed for diisocyanates accounting for a number of factors. Where exposure levels are below the limit of quantification, a default value of 0.25 µg NCO/m3 is assigned and then further reduced by 50% to 0.125 µg NCO/m3 to take account of the REACH Restriction. Then, levels were reduced through a given set of values, and percentiles were calculated using a log normal distribution. Finally, all exposure levels were reduced by 50% to account for the impacts of the REACH restriction.

When considering the assumed impacts of the REACH restriction, however, due to the difficulties regarding the calculation of the benefits, the sensitivity analysis performed is less straightforward than in the case of lead. The sensitivity analysis considered also a reduction in exposure concentrations of 30% and 70% in addition to the retained assumption (50%). A sensitivity analysis was also performed by removing micro enterprises (those with between one and nine employees) in construction and vehicle repairs from calculations of monitoring and administrative costs. Many of these companies employ one person, and data on micro enterprises in construction is difficult to obtain, given the high numbers of self-employed. Since it is likely that many of these companies would not be required to monitor compliance (if it can be proven by other means), including them in the calculations could result in an overestimation of the costs. This results in unchanged benefits but improved cost-benefit ratios.

ANNEX 5: RELEVANT SECTORS, USES AND EXISTING LIMIT VALUES

5.1 Lead

5.1.1 Mining and manufacture of lead

Mining of lead ore takes place in eight Member States as shown in the table below. According to the Euromines (2020), the total lead content of the mined ores increased from 197 000 tonnes in 2008 to 282 000 tonnes in 2018. The two main mining countries are Sweden and Poland. There are seven active lead mines in Sweden, while in Poland exploitation is currently carried out from three deposits (ECHA, 2019).

The total refined lead production in the EU is about 2.7 million t/year, meaning that the mining within the EU in 2018 only accounts for about 10%. The remaining ca. 90% of lead concentrate used for the primary production of lead was imported from countries outside the EU.

The production of refined lead is distributed all over the EU and refining takes place in 18 Member States. The major Member States in terms of production of refined lead are Germany (24.2% of total), Spain (9.8%), Italy (9.5%), Poland (8.8%), and Belgium (7.9%). These figures are from 2014, where the UK contributed with 15.8% of the EU refined lead production. The balance between primary and secondary production has shifted since 1998, and in 2011 secondary sources accounted for more than 77% of EU production (BREF, 2017). Lead-acid batteries are the main source of scrap for secondary refining.

The distribution of lead mining and refined lead production (primary and secondary) can be used as a rough indication of the distribution of workers exposed to lead within these sectors.

Table 1: Mining production and production of refined lead (primary and secondary) by Member State in EU-27 (from 2020)

	Mining production in 2008, t/year*	Mining production in 2018, t/year*	Production of refined lead in 2014, t/year**	Percentage of total production of refined lead
Austria	-	-	37 122	2.6%
Belgium	-	-	133 252	9.4%
Bulgaria	14 600	24 200	92 000	6.5%
Czechia	-	-	44 000	3.1%
Estonia	-	-	8 588	0.6%
France	-	-	72 000	5.1%
Germany	-	-	408 000	28.7%
Greece	16 100	15 300	6 000	0.4%
Ireland, Rep. of	50 300	16 700	17 200	1.2%
Italy	-	-	160 000	11.3%

	Mining production in 2008, t/year*	Mining production in 2018, t/year*	Production of refined lead in 2014, t/year**	Percentage of total production of refined lead
Netherlands	-	-	31 000	2.2%
Poland	47 900	40 200	149 000	10.5%
Portugal	-	-	5 000	0.4%
Romania	-	-	12 000	0.8%
Slovenia	-	-	11 000	0.8%
Slovakia	1 800	100	-	-
Spain	2 400	20 300	166 000	11.7%
Sweden	63 500	64 800	68 708	4.8%
Total	**196 600**	**181 600**	**1 420 870**	**100%**

* *Source: Euromines (2020) at: http://www.euromines.org/mining-europe/production-mineral#Lead. Rounded figures.*

** *Source: USGS, 2017. Mining production expressed as lead content of concentrate. The 2017 publication is the most recent Minerals Yearbook for lead.*

5.1.2 Primary production of lead

The production rate of lead and its compounds in the EU is in excess of 10 million tonnes per year. Occupational exposure of workers happens primarily in industries that produce or recycle lead or use large quantities of lead or lead compounds (such as lead battery production). Exposure also occurs in the ceramics and lead crystal glass sectors and PVC processing[98].

Lead is registered under REACH in the tonnage band 1 000 000 – 10 000 000 tonnes per annum. Its registered uses are:

- Lead battery production;
- lead sheet production;
- lead powder production:
- use of lead metal in the production of a range of lead articles (e.g., cast, rolled and extruded products, ammunition, lead shot):
- use of lead metal in the production of leaded steels;
- use of lead metal in lead oxide production and use of lead oxide in stabiliser production;

5.1.3 Secondary production of lead

The complex waste products used for the production of secondary lead may provide indications of processes, where exposure to lead can occur when generating the wastes. The substances listed in the

[98] SUBSPORT Specific Substances Alternatives Assessment – Lead and its inorganic compounds, March 2013 accessed at https://www.subsportplus.eu/subsportplus/_Downloads/SUBSPORT-Lead.pdf?__blob=publicationFile on 19 January 2021.

following table account for 97.5% of REACH registered tonnage used in the secondary manufacture of lead (ECHA, 2019).

Table 2: Substances used in the secondary manufacture of lead (ECHA, 2019)

EC number	Name	Description
266-970-4	Slags, copper refining	Mainly copper, copper oxides, some oxides of lead and minor metals, skimmed from the anode furnace and returned to the converter.
266-967-8	Matte, copper	Product of smelting roaster calcines concentrates or cement copper with flux in reverberatory or electric furnaces. Composed primarily of copper and copper, iron and lead sulfides with minor sulfides of other metals.
273-760-6	Flue dust, zinc-refining	By-product of refining of zinc ores consisting primarily of zinc, lead and iron.
273-825-9	Slags, lead smelting	Insoluble substance obtained during dissolution of zinc ores or concentrate in sulfuric acid for the production of zinc sulfate solutions after physical separation such as flotation and filtration.
293-314-4	Leach residues, zinc ore, lead-contg.	Insoluble substance obtained during dissolution of zinc ores or concentrate in sulfuric acid for the production of zinc sulfate solutions after physical separation such as flotation and filtration.
308-011-5	Lead, bullion	nan
305-445-7	Wastes, lead battery reprocessing	Material obtained during the recycling of exhausted lead storage batteries. Consists primarily of oxides and sulfates of lead and lead alloys.
273-809-1	Flue dust, lead-refining	By-product of refining lead ores obtained from baghouse and electro-static precipitator and as slurry from scrubbers.
305-411-1	Calcines, lead-zinc ore conc.	A thermally agglomerated substance formed by heating a mixture of metal sulfide concentrates, limestone, sand, furnace dross, miscellaneous zinc, lead and copper bearing materials, together with already roasted material to a temperature of 1000°C to 1200°C (538°F to 649°F).
273-800-2	Slags, lead reverbatory smelting	By-product from the smelting of lead ores, scrap lead or lead smelter dross. Consists primarily of oxides and silicates of antimony and lead.
282-356-9	Matte, lead	Substance resulting from the smelting of lead and its alloys obtained from primary and secondary sources and including recycled plant intermediates. Composed primarily of iron and lead (mainly in sulfide form) and may contain other residual non-ferrous metals and their compounds.
273-796-2	Lead, dross	nan

Note: The table combines information from Table 18 (EC number and name) and Table 40 (description). "Nan" is not explained in the report (ECHA, 2019).

5.1.4 Consumption of lead

"First application" is defined as the first application after refining for which a metal is used. As an example, the first application may be the manufacture of lead compounds, which are later used for various applications such as manufacturing plastics, paints or ceramics. From 2000 to 2015, the trends in the consumption of lead by first applications are shown in the table. The data for 2000, 2005 and 2015 have been obtained from the Lead REACH Consortium (2019) and represent 14 Member States and Norway. The 2015 data represent 94% of the total use of lead for first use in EU28 and EFTA countries. The data include consumption volumes from the UK. The breakdown of data per Member State is not available, the data have therefore not been recalculated to reflect the EU-27 as per 2020. The percentage may be lower or higher for individual applications.

For 2000, also the data from the Voluntary Risk Assessment for Lead are shown (LDAI, 2008). The data represent first applications in the EU15. In 2000, lead additives for gasoline, which are organolead compounds, accounted for about 1% of the total use of lead. The gasoline additives for the 2005 and 2015 datasets are included under lead compounds.

Table 3: Consumption of lead by first use application

Application area (sector numbering according to this study)	Consumption of lead for first use (1000 tonnes)				% of total in 2015
	2000**	2000*	2005*	2015*	
Batteries, automotive (3)	1 009	971	1 033	809	53%
Batteries, industry (3)				460	30%
Rolled and extruded products (4)	242	205	200	95	6%
Shot and ammunition (4)	57	53	50	57	4%
Cable sheathing (4)	31	17	13	18	1%
Gasoline additives [out of scope of study]***	19	202	110	68	4%
Pigments and other lead compounds*** (6)	201				
Miscellaneous (including alloys and solders) (4, 5)	78	67	52	10	1%
Total	**1 677**	**1 515**	**1 458**	**1 517**	**100%**

** Data from Lead REACH Consortium (2019). Data represent the first applications consumption in 14 EU Member States and Norway[99]. The total represents about 94% of the total use of lead for first use in EU28 and EFTA countries. Consumption volumes have not been adjusted to reflect the EU-27 (2020), as national data for the UK is not available. The percentage may be different for the individual applications. The total is similar to the total indicated in the proposal for identifying lead as a SVHC (Substance of Very High Concern) (Swedish Chemicals Agency, 2018) but the distribution between applications is slightly different.*

***Data from the voluntary risk assessment for lead (LDAI, 2008). Represents the consumption in EU15.*

**** Consumption of lead compounds are not differentiated into applications for gasoline additives, pigments and other for 2000 -2015 in the data from Lead REACH Consortium (2019). However, the*

[99] Austria, Belgium, Bulgaria, Czechia, Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Poland, Spain, Sweden, the United Kingdom.

use of lead compounds as gasoline additives is restricted to diminishing amounts in special applications.

The consumption for batteries has been increasing during the period, whereas the consumption for rolled and extruded products has been decreasing.

The decrease in the consumption of lead for the latter three application areas may be used as an indication of a decrease in the number of workers exposed when working with the lead-containing products (the decrease in the number of workers may be even higher than the decrease in the lead consumption).

The following includes a short description of the uses of lead metal.

Rolled and extruded products. These products consist of lead plates, sheets, strips, bars, wires and tubing produced through a combination of rolling, drawing and extruding. Lead sheet accounts for the majority of lead used in this category and 85% of lead sheet is used in construction applications, with the remainder used in various medical, nuclear, defence and industrial applications (Lead REACH Consortium, 2019). Due to differences in architectural style and building techniques, the use of lead sheet varies considerably among Member States. During the period 2005-2015, the UK has accounted for approximately half of the use of lead in rolled and extruded products. This is of importance for the interpretation of data on the number of exposed workers related to the building sector.

Shot and ammunition. The consumption of lead for the production of ammunition has been stable during 2000-2015 (Lead shot accounts for an estimated 75% of the lead used in non-military shot/ammunition, while lead pellets and bullets account for the remaining 25% (Lead REACH Consortium, 2019). Major civilian ammunition manufacture in Europe is concentrated in Italy, followed by Germany, Spain, the UK, Sweden, Czechia and France.

Miscellaneous. Lead is used as an alloying additive to other metals, typically to improve castability, finishing and plating characteristics. Lead is used as an alloying element for tin, steel, copper (brasses and bronzes) and aluminium alloys. The total consumption for miscellaneous applications has decreased markedly from 67 000 t/year in 2000 to 10 000 t/year in 2015. Lead was widely used in white metal and pewter (tin-lead alloys) models, ornaments and jewellery. Lead solders, the alloys used to create metallurgical bonds between two or more metal surfaces to achieve an electrical and/or physical connection, once dominated both electronic and industrial applications. The use of lead solders in electrical and electronic equipment (EEE) has been banned since 2006, with some exemptions, but the exemptions gradually expire and are often not renewed. According to the Lead REACH Consortium (2019), there is also a move away from the use of lead solder in industrial applications, such as in the joins to copper or brass heat exchangers and the solder for joining copper, brass and zinc in roofing, and rainwater furniture.

5.1.5 Consumption of lead compounds

The main uses are described below:

Batteries. Lead-acid battery manufacture is the largest application for lead and lead compounds in Europe: lead oxides are pressed, cured, hydrated and then reacted with sulphuric acid to produce porous metallic lead negative electrode pastes (Lead REACH Consortium, 2019). Lead sulphates can be used as seeding material for the lead dioxide, the active material at the positive electrode. Lead-acid batteries are the leading rechargeable battery technology, at over 90% of the rechargeable battery market in terms of energy stored. Key countries for lead-based battery manufacture in Europe include

Czechia, France, Germany, Italy, Spain, Poland and the United Kingdom (ECHA, 2019). About 99% of lead monooxide tonnage used in the EU (500 000 tonnes) and about 80% of lead tetraoxide tonnage (36 000 tonnes) is used in battery manufacture. They are transformed in the course of the battery manufacturing process into pentalead tetraoxide sulphate and tetralead trioxide sulphate, which are themselves ultimately transformed within the battery into lead metal and lead dioxide (ECHA, 2019).

Plastic stabilisers. Lead stabilisers based on lead sulphates, phthalates and stearates have traditionally been added to both rigid and flexible PVC to improve their physical properties and durability. As of the end of 2015 under the VinylPlus voluntary commitment, all lead-based PVC stabilisers have been completely replaced in formulations for PVC applications sold in the EU28. The alternatives are predominantly calcium-based stabilisers. In 2005, approximately 60 000 tonnes lead were used for PVC stabilisers in the EU15. The consumption has gradually decreased from 2005 to 2015. Although lead stabilisers are no longer used in virgin PVC in the EU28, some lead stabilisers are still produced in Europe for export to other regions. According to the Annex to the Restriction on the use of lead compounds to stabilise PVC (ECHA, 2018), the European Stabiliser Producers Association (ESPA) representing more than 95% of PVC stabiliser industry across EU indicated that in 2016 there was only one European company producing lead stabilisers for export to non-EU countries. The Annex also notes that approximately 30% of EU-produced lead stabilisers are exported outside the EU, which means that 70% remains within the EU. According to the proposed REACH restriction of the use of lead stabiliser, PVC with lead stabilisers may still be recycled for certain uses.

Pigments. The major lead pigments are lead chromates, which are subject to authorisation (due to the content of hexavalent chromium in the compounds). The total authorised quantities are 3 000 t/year. According to the Lead REACH Consortium (2019), pigments based on lead carbonates (white) and lead oxide (red) are used now only in niche applications such as paint for restoring or maintaining works of art or historic buildings. For the vast majority of uses in the EU, lead pigments have been replaced with other pigments such as titanium dioxide. For red lead oxide, there is only one professional use of the substance in paints included in the joint registration dossier, which is for rust-inhibiting priming paints applied directly to iron and steel (mainly ships) because of its anti-corrosion properties.

Glasses. Leaded glass typically contains 54-65% of SiO_2, 24-30% PbO (lead oxide), 13-15% Na_2O or K_2O and various minor components (Lead REACH Consortium, 2019). Leaded glass has a higher density and refractive index than most other glasses and is used in decorative applications e.g. wine glasses, tableware and decanters. Lead crystal production has historically been concentrated in Europe and has declined steeply over the last decade (Lead REACH Consortium, 2019). France, Germany, Ireland, Czechia and Slovakia still have some lead glass production remaining and the lead use in crystal glass in European countries has been estimated at 3 000 – 5 000 t/year (Lead REACH Consortium, 2019). In the EU, only glass products containing at least 24% of PbO may be referred to as "lead crystal". Products with less lead oxide must be labelled "crystalline" or "crystal glass" (ECHA, 2019).

Lead glass is also used for various types of optical and filter glasses e.g., camera and microscope lenses. Lead glass has been granted an exemption under the RoHS (Restriction of Hazardous Substances) Directive (Directive 2011/65/EU) until 2021.

Frits (ceramics). Frits, a term for the coloured precursors to ceramic glazes and glass colouring, can contain lead compounds. Overall, the use of lead in frits and pigments is decreasing due to the availability of lead-free alternatives and the costs associated with ensuring regulatory compliance when using lead-containing compounds in a workplace (Lead REACH Consortium, 2019).

5.1.6 Biological limit values

Table 4: Biological limit values in EU Member States and selected non-EU countries for lead (status: 28.06.2021)

Country	Lead in blood µg Pb/100 ml	Specification	Country	Lead in blood µg Pb/100 ml	Specification
Austria	70 45	-men, women >50 years -women <50 years	Portugal	70	
Belgium	70		Romania	70	-health surveillance for workers at > 40 µg/100 ml
Bulgaria	40 30	-women <45 years	Slovakia	40 10	-women <45 years
Croatia	40 30	-women <45 years	Slovenia	40 30	-women <45 years
Cyprus	70		Spain	70	-mandatory health surveillance for workers at > 40 µg/100 ml
Czechia	40		Sweden	31.1(<1.5 µmol/l) 10.4(<0.5 µmol/l	-men, women >50 years -women <50 years
Denmark	20				
Estonia	-		European Union	70	-mandatory health surveillance for workers at > 40 µg/100 ml
Finland	29 (1.4 µmol/l)		RAC	15 4.5	-for lead and its inorganic compounds -women of childbearing age
France	40 30	-male -female	Australia	30	-men and women not of reproductive

Country	Lead in blood µg Pb/100 ml	Specification	Country	Lead in blood µg Pb/100 ml	Specification
	18	-recommended value by ANSES		10	capacity -women of reproductive capacity
Germany	15		Brazil	-	
Greece	70		Japan - JSOH	15	-except alkyl compounds
Hungary	30 (1.5 µmol/l) 20 (1.0 µmol/l)	-men, women >45 years -women <45 years	Norway	0.5 µmol/l 1.5 µmol/l	-women of childbearing age other workers
Ireland	70	-health surveillance for workers at > 40 µg/100 ml	Russia	-	
Italy	60 40	-health surveillance for workers at > 40 µg/100 ml -women at childbearing age	South Korea	-	
Latvia	60	-health surveillance for workers at > 40 µg/100 ml	Switzerland	40 10	-men, women >45 years -women <45 years
Lithuania	70		Turkey	70	
Luxembourg	70		United Kingdom	60 30	-men -women of reproductive capacity
Malta	70		USA, ACGIH	20	
Netherlands	60		USA, NIOS	60	
Poland	50		USA, OSHA	50	

Table 5: OELs in EU Member States and selected non-EU countries for lead (status: 28.06.20)

Country	OEL [mg/m³, (ppm)]	Specification	Country	OEL [mg/m³, (ppm)]	Specification

Austria	0.1 (I)	for lead compounds except alkyl lead compounds; R1, L	Slovakia	0.5 (R) 0.15 (I)	
Belgium	0.15		Slovenia	0.1 (I)	R1
Bulgaria	0.05		Spain	0.15 (I)	R1
Croatia	0,15†	except lead chloride fluoride iodide; R1	Sweden	(I) 0.05 (R)	R
Cyprus			EU	0.15(I)†	
Czech Republic	0.05	for lead compounds except alkyl lead compounds	Australia	0.05	Dusts and fumes
Denmark	0.05 (I)†		Brazil	0.1	
Estonia	(T) 0.05 (R)	R R	Canada, Ontario	0.05	leemental, inorganic and organic compounds of lead, except tetraethyl lead
Finland	0.1 †		Canada, Quebec	0.05	K
France	0.1 (I)	restrictive statutory limit value; K, R	China	0.05 (I) 0.03 (R)	
Germany	0.15 (I) † 0.1	R1, L reference value*; R1, L	India	0.15	Dusts and fumes
Greece			Japan	0.05	
Hungary	0.10 0.05 (R)		Japan JSOH	0.03	for lead compounds except alkyl lead compounds; K, R1
Ireland	0.15†	R1	Norway	0.05†	dusts and fumes; except lead acetate, lead phosphate, lead chromate and lead subacetate; R
Italy	0.15		Russia	0.05	aerosol
Latvia	0.05		South Korea	0.05	K, R1
Lithuania	0.15 (I)	except lead	Switzerland	0.1 (I)	except alkyl

	0.07 (R)	sulphide; R except lead sulphide; R			lead compounds; K2,R1
Luxembourg	0.15		Turkey	0.15	
Malta	0.15†		United Kingdom	0.15	except alkyl lead compounds
Netherlands	0.15 (I)†		USA, ACGIH	0.05	K
Poland	0.05 (I)	except lead arsenate and lead chromate	USA, NIOSH	0.05(T)	
Portugal	0.15		USA, OSHA	0.05 (T)	
Romania	0.15				

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 fraction/aerosol

(R) = respirable fraction/aerosol

(T) = total dust

K = carcinogenicity notation assigned

K1 = assigned as Carc. Category 1A or 1B

K2 = assigned as Carc. Category

R = notation as reproductive toxin assigned

R1 = assigned as Repr. Category 1A or 1B

L = notation for effects on or via lactation assigned

* reference value that represents the state of the art. Individual measures are related to this limit value.
† binding limit value, if explicitly stated by the member state

**NIOSH indicates a time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek.

5.2 Diisocyanates

5.2.1 Overview of uses

Diisocyanates are important industrial chemicals that have several applications; these can primarily be categorised as:

- Polyurethane;
- CASE:
  - **C**oatings (surface treatment like paints and lacquers);
  - **A**dhesives;
  - **S**ealants (e.g., fillers/joint fillers); and
  - **E**lastomers (e.g., rubber and thermoplastic elastomers).

The use of diisocyanates consists of manufacturing and professional uses.

Diisocyanates are used as a raw material in the production of all polyurethane products. Polyurethane foams (flexible and rigid) are strong, durable, resistant to abrasion, resistant to corrosion, have low thermal conductivity, and easily fill voids, and can be shaped. Combined, these properties make polyurethane foams ideal for use in insulated building panels, mattresses, upholstered furniture, car seats, domestic refrigerators, freezers, composite wood panels, truck bodies and footwear.

Diisocyanates may be present at concentrations of between 0-50% in coatings/paint products and 0.01-90% in adhesive and sealant products (Danish Environmental Protection Agency, 2014). CASE products are widely used and occupational exposure may occur during both the manufacturing of the relevant products as well as professional use. This includes settings such as construction, manufacturing of electrical and related equipment, manufacturing of shoes and textiles, manufacturing of wood, transport and machinery manufacturing, and the repair of transport and machinery.

PMDI is used to produce both flexible and rigid foams (typically rigid foam is used in metal insulation). insulation boards and cool chain applications (fixed and mobile refrigeration and freezers). Flexible foam manufacturing is the largest consumer of TDI by volume and second largest consumer of MDI. The largest consumer of MDI is the rigid foam sector (in the form of pMDI) and the elastomer sector. CASE products typically contain MDI, HDI or TDI. The table below subdivides the 2011 MDI and TDI consumption data for volumes on the EU market (EU27+Norway) into the main application categories.

Insulating products manufactured with diisocyanates contribute highly to the EU's food and medicine quality, and also significantly contribute to business and residential energy savings. CASE products are currently widely used, and the product properties contribute significantly to the sectors they are used in.

Table 5: Yearly MDI and TDI consumption data for EU (plus Norway) subdivided into main application areas.

EU27+Norway (2011)	Polymeric MDI (pMDI) (t/year)	Monomeric MDI (t/year)	TDI (t/year)	Total MDI and TDI (t/year)	Speciality Diiso cyanates (t/year)
Adhesives	17 900	28 500	18 300	64 700 (4%)	11 600
Coatings	35 500	10 900	30 100	76 500 (5%)	66 800
Elastomers	0	101 500	2 500	104 000 (7%)	5 300
Sealants	5 300	6 700	4 400	16 400 (1%)	600

EU27+Norway (2011)	Polymeric MDI (pMDI) (t/year)	Monomeric MDI (t/year)	TDI (t/year)	Total MDI and TDI (t/year)	Speciality Diiso cyanates (t/year)
Binders	145 900	0	500	146 400 (10%)	0
Flexible Foam	83 400	32 700	305 200	421 300 (27%)	0
Rigid Foam	708 000	0	0	708 000 (46%)	0
Total	996 000	180 300	361 000	1 537 300	84 300

Source: IAL Consultants (2013) as reported by the Danish Environmental Protection Agency (2014).
Notes: IAL Consultants roughly estimates that the uncertainty on these figures is about 5% (+/-)

5.2.2 Existing limit values

There are 18 MSs with an OEL, but they are mostly for specific diisocyanate compounds and are based on the molecular weight of each specific diisocyanate compound and not on the NCO group. For this reason, it is not possible to present a table that gives a meaningful comparison of the levels at which the limits are set. Only Croatia, Ireland and Lithuania have general diisocyantes OELs.

The table below present the range of the national OELs after converting the level from molecular weight of the specific compound to the -NCO grouping approach.

Table 6: Maximum, minimum and average of NCO OELs (µg/m³, 8-h TWA) in EU Member States for diisocyanates

Maximum, minimum and averages	All compounds
Maximum	500
Minimum	3
Median	17.4
Mode	16.8
Mean	26.7

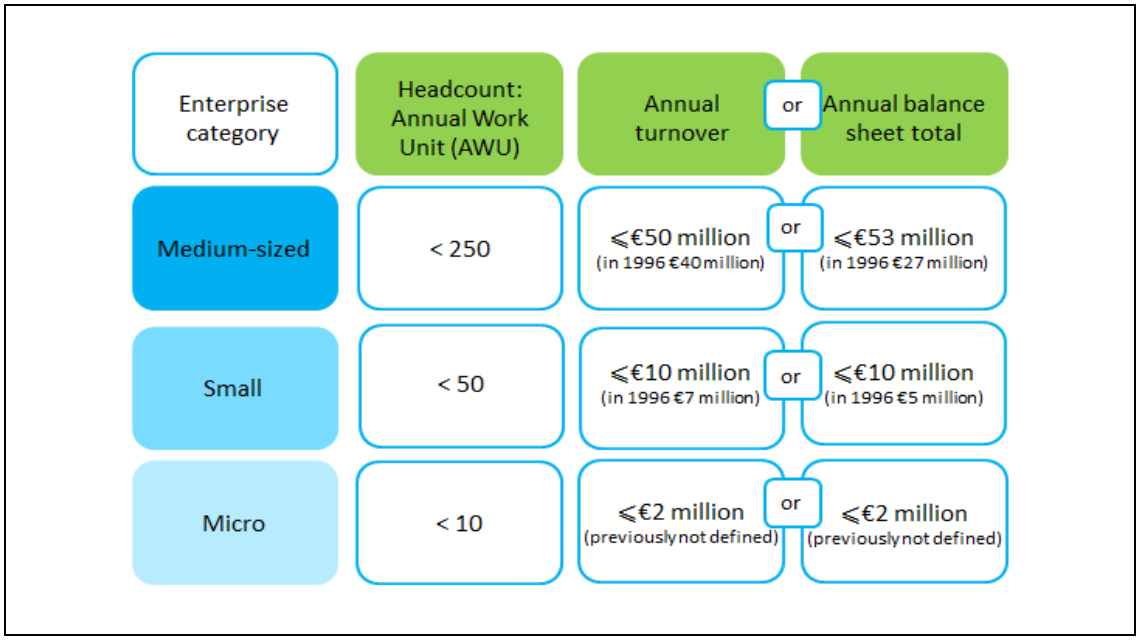
Source: Study team (calculated January 2021)

ANNEX 6: SMES

6.1 SMEs

An enterprise is considered to be a medium-sized, small or micro enterprise depending on thresholds that have been outlined by the Commission.

Figure 1 Categorisation of SMEs



SMEs can be proportionately higher impacted by regulatory changes that introduce substantial adjustment or administrative costs. Their limited size often makes it more difficult to access capital, and most often at a higher cost of capital than large enterprises.[100] SMEs can therefore be exposed to proportionally higher costs, as compared to the large enterprises.

The numbers of small, medium, and large enterprises likely to have workers exposed to lead and diisocyanates in the EU is estimated in the tables below. The vast majority of companies with exposed workers and which are likely be affected by the limit value options are SMEs.

6.2 Lead

The table below presents the estimated share of small and medium enterprises as well as the total share of SMEs out of all EU enterprises with exposed workers. Most of the covered sectors are dominantly composed of SMEs. Many of the sectors entail however less than 100 enterprises across Europe. Sectors with a high share of SMEs as well as a high number of enterprises (i.e., above 1 000) are sectors working with lead metal (sector 10), shooting ranges (sector 11), and the demolition,

[100] Tool # 22 of the Better Regulation toolbox on SMEs.

repairing, and scrapping industry (sector 13); of which the latter is likely to pass on costs to consumers. These sectors moreover consist of nearly exclusively small enterprises. Looking across all sectors, small enterprises comprise the dominating share in eight (out of 15) sectors.

When measured by the number of enterprises, thus, the majority of enterprises that would need to comply with a stricter BLV would primarily consist of SMEs.

Table 1: Distribution of EU enterprises with exposed workers by small and medium size, as well as total share of SMEs out of EU enterprises with exposed workers by sector

Sector	Share of no. of enterprises by size			Total no. of enterprises
	Small <50 employees	Medium 50-249 employees	Total SMEs	
1. Primary lead production	0%	0%	0%	6
2.Secondary lead production (including lead battery recycling)	15%	63%	78%	43
3. Lead battery production	0%	22%	22%	32
4. Production of articles of lead metal	47%	32%	79%	26
5. Foundries	59%	31%	90%	180 (90-270)
6. Production of lead compounds and lead frits	10%	50%	60%	11
7. Production of glass	76%	13%	89%	46
8. Ceramic ware production and enamelling	96%	3%	99%	26
9.Manufacture and use of plastics and paints	80%	10%	90%	84
10. Work with lead metal	90%	10%	100%	3,125 (1 250 – 5 000)
11. Shooting ranges	100%	0%	100%	4,000 (3 000 – 5 000)
12. Recycling of PVC and other plastics	75%	25%	100%	100
13. Demolition, repairing and scrap industry	91%	8%	99%	14 179
14. Other waste handling and remediation	75%	25%	100%	700
15. Other (Copper production)	0%	80%	80%	7

Source: Eurostat (2018).

6.3 Diisocyanates

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

Table 2: Distribution of EU enterprises with exposed workers by size of enterprise by sector (percentages)

NACE - Sector	Number of enterprises			
	Small	Medium	Large	Total
C13 Textiles	96.56%	2.96%	0.48%	100%
C14 Apparel	97.50%	2.00%	0.50%	100%
C15 Leather	96.10%	3.42%	0.48%	100%
C16 Wood	97.50%	1.50%	1.00%	100%
C20 Chemicals	88.00%	9.00%	3.00%	100%
C22.21 Rigid foam	53.00%	35.00%	12.00%	100%
C22.29 Flexible foam	87.00%	9.00%	4.00%	100%
C22 Other	53.00%	35.00%	12.00%	100%
C26 Computers	92.00%	6.00%	2.00%	100%
C27Electrical equipment	86.00%	10.00%	4.00%	100%
C28 Machinery	93.00%	6.00%	1.00%	100%
C29 Motor vehicles	83.00%	10.00%	7.00%	100%
C30 Transport	92.00%	6.00%	2.00%	100%
C31 Furniture	97.87%	1.80%	0.33%	100%
C33 Machinery repair	98.25%	1.50%	0.25%	100%
F41.2 Construction	99.21%	0.73%	0.06%	100%
F42 Civil engineering	95.00%	4.00%	1.00%	100%
F43Specialised construction	99.56%	0.40%	0.04%	100%
F43.29Other installation	99.39%	0.55%	0.06%	100%
G45.2 Vehicle repair	99.80%	0.17%	0.03%	100%
S95 Repairs	99.93%	0.06%	0.01%	100%

Source: Eurostat (2018).

ANNEX 7: PROCESS FOR SETTING BINDING OELS, BLVS AND ASSOCIATED PROVISIONS

What are limit values?

Occupational Exposure Limits

OELs are the limit of the Time-Weighted Average (TWA) of the concentration for a chemical in the air within the breathing zone of a worker in relation to a specified reference period (normally 8 hours).

Short Term Exposure Limits

STEL values, usually involving a 15-minute reference period are used when adverse health effects are not adequately controlled by compliance with an 8-hour TWA OEL, e.g. for substances for which a critical effect is observed following a brief exposure (e.g. acute toxic substances, substances causing nuisance, irritation, central nervous system depression, sensitisation).

Biological Limit Values

BLVs are the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect (in the case of lead, in the blood of the exposed worker).

Notations

OELs, STELs and/or BLVs can further be annotated with appropriate indications of additional body burden resulting from non-inhalation routes such as, for example, a 'skin' notation where the dermal route of exposure is scientifically considered to be relevant.

The European Agency for Safety and Health at Work (EU-OSHA), in a European risk observatory report[101], states that OELs are one of the major control instruments for workers' exposure to chemicals; they belong to the most important tools for exposure assessment and management.

The advantages of limit values are that they provide clarity and objectivity. They are very relevant quantitative benchmarks for employers enabling them to know exactly the levels above which exposure cannot occur. Limit values also allow employers to determine the level below which their risk management measures should aim to comply with the obligation to eliminate or to minimise the exposure to as low a level as possible[102].

Limit values 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

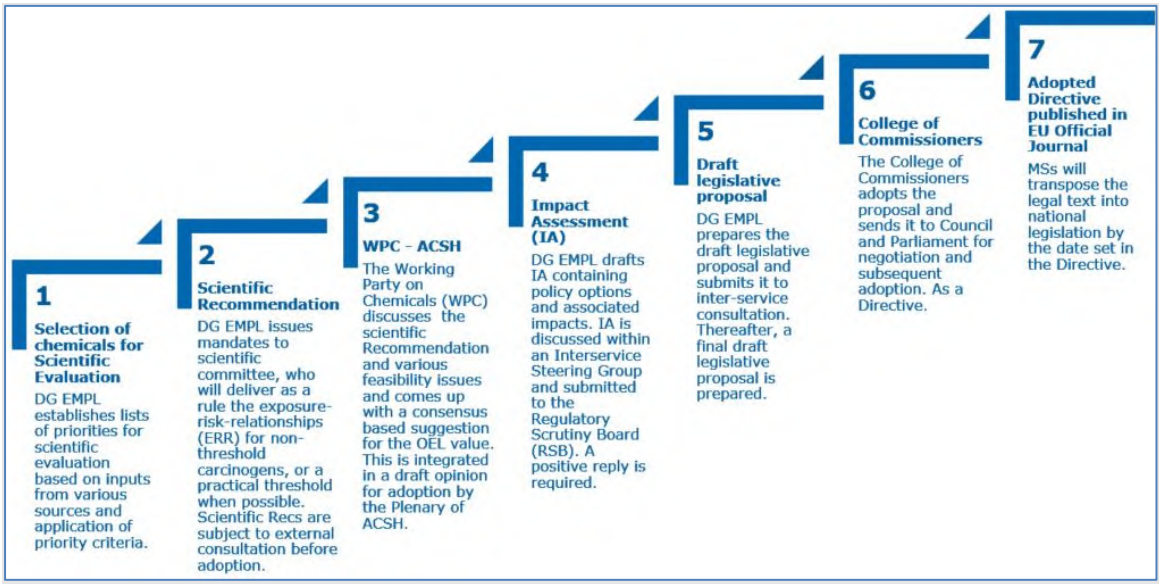
[101] https://osha.europa.eu/en/publications/exploratory-survey-occupational-exposure-limits-oels-carcinogens-mutagens-and

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

below the limit values. They inform employees about the risks which exposure can cause and put them in a position to check that the necessary protective measures are taken to protect their health.

The figure below summarises the process of setting EU limit values.

Figure 1: simple representation of EU limit value setting procedure (Source: ECHA website)



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 2020 - 2021 and addressed the amendment of CAD and CMRD. 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 substances 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 ill-health occupational 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, reprotoxic etc) which could be prevented by establishing an EU level OEL and/or BLV.

The Commission is committed to continuing efforts to strengthen the application of such criteria in the future.

Step 3: Scientific evaluation and public consultation

Article 3 of the CAD and article 16 of the CMRD state that scientific/feasibilty data should be included in the basis on which binding OELs and BLVs are set, but the directives do 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, 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 (BLVs)/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. conclusions of national limit vlaue-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 lead and diisocyanates 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 CMRD 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 limit value (OEL, STEL or BLV) for a substance 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 the priority substances foreseen for this amendment of CAD and CMRD.

In practice, a limit value 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 the limit values exist within the broader context of the CAD and CMRD general obligations to prevent risks to workers' health (exposure elimination/reduction, process enclosure etc.), which establishes an appropriate and exceptionally high legal standard for workplace- and process-specific risk control.

Step 5: Impact assessment

Between 2020 and 2021, an external contractor evaluated, on behalf of the Commission, health, socioeconomic and environmental impacts of the proposed amendments to CAD and CMRD 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.

An option is retained if the ACSH opinion has been clear and consensual, there are no concerns about the 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.

A positive opinion 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 States will then transpose the limit values and any associated notation into their national legislation by the date set in the Directive.

The limit values 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 limit values.

Within the CAD and CMRD there are obligations for employers to apply the appropriate measures at the workplace to ensure that the exposure of workers to these substances do not exceed the limit values. The monitoring of the correct implementation of the national legislation that transposes the EU directives and enforcement will be undertaken by national authorities, in particular the national labour inspectorates.

ANNEX 8: CONSISTENCY AND COMPLEMENTARITY WITH THE REACH REGULATION

Restrictions under REACH[103]

Lead carbonates (restriction no. 16) and lead sulphates (restriction no.17)

Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint. However, Member States may, in accordance with the provisions of International Labour Organization (ILO) Convention 13, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors, as well as the placing on the market for such use.

Lead and its compounds

Lead and its compounds (restriction no. 63) are restricted under the REACH Regulation and shall not be placed on the market or used in any individual part of jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0.05 % by weight.

Name of agent in Annex XVII	Entry No.	Conditions of the restriction
Lead and its compound	63	https://echa.europa.eu/documents/10162/654a4f38-ebdb-b3b0-bda0-892bd44001de

In addition, lead [CAS No 7439-92-1] has been identified as an SVHC and placed on the candidate list for inclusion into Annex XIV since June 2018, on the grounds that it is a substance toxic to reproduction.

There is also a general restriction (no. 30) concerning reprotoxic substances that shall not be placed on the market, or used as substances, as constituents of other substances, or in mixtures, for supply to the general public.

Diisocyanates

Diisocyanates are restricted under the REACH Regulation and shall not be used or placed on the market as substances on their own, as a constituent in other substances or in mixtures for industrial and professional uses unless the employer or self-employed ensures that industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the

[103] https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&_disslists_WAR_disslistsportlet_orderByCol=prc_entry_no&_disslists_WAR_disslistsportlet_substance_identifier_field_key=&_disslists_WAR_disslistsportlet_delta=50&_disslists_WAR_disslistsportlet_orderByType=asc&_disslists_WAR_disslistsportlet_doSearch=&_disslists_WAR_disslistsportlet_prc_entry_no=&_disslists_WAR_disslistsportlet_deltaParamValue=50&_disslists_WAR_disslistsportlet_resetCur=false&_disslists_WAR_disslistsportlet_cur=1

substance(s) or mixture(s). A Commission Regulation was also recently adopted amending Annex XVII to REACH and introducing detailed training requirements for workers[104].

Name of agent in Annex XVII	Entry No.	Conditions of the restriction
Diisocyanates	74	https://echa.europa.eu/documents/10162/503ac424-3bcb-137b-9247-09e41eb6dd5a

The combination of REACH Restriction and OSH provisions, especially a binding OEL and health surveillance established in the frame of CAD is the most efficient approach for preventing peak exposure which is the key event leading to asthma from exposure to diisocyanates.

[104]See footnote 65.