EUROPEAN
COMMISSION

Brussels, 28.6.2021
SWD(2021) 158 final

COMMISSION STAFF WORKING DOCUMENT

ANALYTICAL DOCUMENT

Accompanying the document

CONSULTATION DOCUMENT

Second phase consultation of the social partners under Article 154 of the Treaty on the Functioning of the European Union, on the protection of workers from risks related to exposure to chemical agents at work and to asbestos at work

{C(2021) 4529 final}

TABLE OF CONTENTS

INTRODUCTION

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. With OSH being put high on the political agenda[1], limit values and other provisions have been set or revised for many substances or groups of substances under the Carcinogens and Mutagens Directive 2004/37/EC and the Chemical Agents Directive 98/24/EC.

In the context of permanently changing world of work and broader policy developments, the Commission announced in the European Pillar of Social Rights Action Plan[2] that, subject to the outcome of the ongoing consultation of social partners, it will present legal proposals in 2022 to further reduce workers' exposure to hazardous chemicals, including asbestos. It will also present in 2021 a new EU OSH Strategic Framework 2021-27, to update protection standards for workers and tackle new and traditional work-related risks such as hazardous chemicals.

Improving workers health by protecting them from exposure to carcinogens, reprotoxins and other hazardous chemicals is in line with President von der Leyen's 2020 State of the Union address[3], where she underlined that health is a top EU priority. It would also be an important contribution to 'Europe's Beating Cancer Plan'. Furthermore, improved protection of workers exposed to asbestos, lead and diisocyanates – substances that are subject to this consultation – will be important in the context of the green transition, and the European Green Deal[4], which is at the heart of this Commission's agenda.

Inadequate control of hazardous chemicals at the workplace is associated with significant costs to individuals and society as a whole. Direct costs of work-related cancer alone in terms of healthcare and productivity losses amount at least to some EUR 4-7 billion per year. The indirect costs may reach as much as EUR 334 billion each year[5]. The long-term care aspect is particularly important for occupational cancer and other illnesses such as impaired cognitive development of the affected offspring.

The fight against occupational cancer and dealing with dangerous chemicals continues to a high priority in the area of occupational safety and health, as stated in the Commission Communication on "Safer and Healthier Work for All"[6] and in the European Pillar of Social Rights Action Plan. Good OSH is essential also for recovery from the effects of

---

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

2 COM(2021) 102 final, 4.3.2021

3 https://ec.europa.eu/info/sites/info/files/soteu_2020_en.pdf

4 European Green Deal

5 RIVM Report 2016-0010: Work-related cancer in the European Union: Size, impact and options for further prevention, Jongeneel WP, Eysink PED, Theodori D, Hamberg-van Reenen HH, Verhoeven JK.

6 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" COM/2017/012 final. http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=2709

COVID-19, as it reduces disruptions at work due to absenteeism and contributes to productivity and competitiveness.

Workers protection from chemicals subject to this consultation is in line with these policy priorities, with **asbestos** (a major occupational carcinogen) playing an important role in the safe renovation of buildings, **lead** (a major reprotoxin) being a key component of battery production for electric vehicles, and **diisocyanates** (asthmagens) being widely used in the manufacture of polyurethane foams, plastics, coatings, varnish, two-pack paints and adhesives and lead.

The main legislative tool to ensure workers' protection against risks related to exposure to **asbestos** is the Asbestos at Work Directive (AWD)[7].

The European Parliament is working on its legislative own-initiative report on asbestos (2019/2182(INL[8]. One of the elements of this report is focusing on the lowering of the existing limit value for asbestos. This is what the updating of the Asbestos at Work Directive would aim to bring forward.

Occupational cancer is, with a share of 52 %, the first cause of work-related deaths in the European Union[9], compared with circulatory illnesses (24 %) and injuries (2 %) and all other causes (22 %). It is primarily caused by exposure to carcinogenic substances with asbestos being the major contributor.

Lead and diisocyanates are both regulated through the Chemical Agents Directive (CAD)[10], the fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC[11].

Estimates show that between 27 and 1274 new cases[12] of reproductive ill health will occur each year, with **lead and its compounds** being the major reprotoxin[13]. Reproductive health problems can present two groups of different effects: one on sexual function and fertility, and other on development of the foetus or offspring (developmental toxicity[14]).

Occupational asthma is an allergic reaction that can occur in some people when they are exposed to substances such as **diisocyanates** in the workplace.

---

7 Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work) (OJ L 330, 16.12.2009, p. 28–36)

8 Draft report with recommendations to the Commission on protecting workers from asbestos

9 EU OSHA (2017): What are the main work-related illnesses and injuries resulting in death and in DALY? Available at: https://visualisation.osha.europa.eu/osh-costs

10 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, (OJ L 131, 5.5.1998, p. 11-23)

11 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, (OJ L 183 , 29.6.1989, p. 1-8)

12 For reproductive health, only workers (both females and males) aged less than 46 years are considered

13 Study to collect recent information relevant to modernising EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes

14 For example, spontaneous abortion, stillbirth or impaired cognitive development of the conceived children

It is important to ensure that risks to workers arising from exposure to chemicals at the workplace are effectively controlled, including, where appropriate, by establishing new EU limit values or revising existing ones. Establishing and updating occupational exposure limits (OELs) in the light of new information is not only a legal requirement under the Directives, but is also called for by social partners, tri-partite stakeholders and the co-legislators. In response to those calls, the European Commission started **preparatory work with the aim of a possible revision of the AWD and the CAD.**

The objective is to improve the relevance and effectiveness of the Directives by establishing or reviewing binding occupational or biological limit values for asbestos, lead and diisocyanates. The Commission aims to increase protection for workers, and improve the length, quality and productivity of the working lives of European workers, while contributing to legal certainty and an improved level playing field for businesses across the EU.

Between 17 December 2020 and 11 February 2021 the Commission conducted a first phase consultation of the European social partners[15], in accordance with Article 154 of the Treaty on the Functioning of the EU (TFEU), on the possible direction of European Union action concerning further revisions of those Directives.

This document provides an overview of the results of the first phase consultation and an analytical background (including a summary of the current situation across Member States for asbestos, lead and its compounds, and diisocyanates) to a second phase consultation of the European social partners on possible legislative action. It identifies the problems to be addressed through the initiative, presents the objectives of an EU intervention and explores the added value of EU action[16]. The document also gives first indications to the expected impacts of the possible avenues of EU action set out in the second phase consultation document.

1 RESULTS OF THE FIRST PHASE SOCIAL PARTNERS CONSULTATION

The Commission consulted the social partners between 17 December 2020 and 11 February 2021 on the establishment or revision of binding occupational limit values for lead and its compounds and diisocyanates under chemical agents at work Directive and for asbestos under Asbestos at work Directive.

In addition, the Commission consulted institutions and stakeholders, in particular the Working Party on Chemicals (WPC) of the Advisory Committee on Safety and Health at Work (ACSH), where the three interest groups of workers, employers and governments are represented.

[15] Consultation Document of 17.12.2020, First phase consultation of the social partners under Article 154 of the Treaty on the Functioning of the European Union, on the protection of workers from risks related to exposure to chemical agents at work and to asbestos at work, C(2020) 8944 final

[16] http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf

1.1 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 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. Concerning question 3, ETUC gave detailed comments on each substance and EFBWW on asbestos.

Asbestos

The workers organisations, while supporting the revision of the current occupational exposure limit (OEL), requested for a broader scope in the action under the Asbestos at Work Directive and beyond.

ETUC and EFBWW proposed that the Directive is updated further than the current OEL. Among others, they suggested widening the scope to include an updated list of all known forms of fibres with similar harmful effects on human health, to cancel the concepts of sporadic exposure and low intensity exposure, and of friable and non-friable asbestos containing materials and the prohibition of encapsulation and sealing of asbestos. Other suggestions were also made in different aspects[17], most of which are already covered by the Directive.

Apart from the revision of the Asbestos at Work Directive, ETUC and EFBWW suggested actions that largely go beyond the scope of safety and health at work. In particular, they asked to create a new European legal framework for national asbestos removal plans, which should include a model with minimum standards for digital asbestos registries, a proposal for mandatory screening before selling or renting out a building and establish asbestos certificates for buildings built before 2005, and financial support to building owners for the save removal of asbestos. Furthermore, they called on the Commission to propose a targeted amendment to Article 7 of Directive 2010/31/ EU[18] on the energy performance of buildings in the context of the Renovation Wave Strategy[19].

In addition, they expressed the need for a legislative proposal for robust European minimum standards for the recognition and adequate compensation for victims of asbestos related occupational diseases, although this is Member States' competence.

[17] For example, provision of technical minimum requirements to lower the concentration of asbestos fibres; representative sampling of the personal exposure of the worker; plan of work shall be drawn up before any work in relation to asbestos starts,

[18] Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings. **OJ L 153, 18.6.2010, p. 13–35**

[19] COM(2020) 662 final

They also asked for the update of Recommendation of 19 September 2003 concerning the European schedule of occupational diseases, to include all known asbestos related diseases [20].

Both trade unions also suggested that in the framework of the new EU Circular Economy Action Plan[21], the registration of asbestos in existing buildings and infrastructures should be a first step to eliminate asbestos from the circular economy

Furthermore, EFBWW expressed views that women workers are vastly underrepresented in research into the health risks that are associated with workplace exposure to asbestos and considered necessary that the Commission includes a specific focus on the gender differences in this and its future initiatives to improve workers' protection from risks related to asbestos.

Lead and its compounds

ETUC, while in principle supported reducing the current limit values, expressed views that the proposed biological limit value (BLV) in the scientific opinion released by the Committee for Risk Assessment of the European Chemicals Agency would be discriminatory for women at the workplace[22]. 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[23] in this context.

Diisocyanates

ETUC, supported that 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 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 EU 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 sees no need to launch a negotiation procedure pursuant Article 155

[20] **OJ L 238, 25.9.2003, p. 28–34**

[21] European Parliament resolution of 10 February 2021 on the New Circular Economy Action Plan (2020/2077(INI))

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

[23] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding. **OJ L 348, 28.11.1992, p. 1–7**

TFEU concerning the revision of the Chemical Agents Directive and Asbestos at Work Directive to make progress on this.

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.

1.2 Employers' organisations

Three employers' organisations replied to the first phase consultation: BusinessEurope, SMEunited (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.

BusinessEurope and SMEunited 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, SMEunited 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.

Asbestos

The employers' organisations recognised that asbestos is a serious threat for workers, which needs to be addressed. BusinessEurope and SMEunited stressed that any revision

of an OEL must be based on sound scientific evidence and a thorough assessment of technical and economic feasibility and socio-economic impact, for which the role of ACSH is central.

BusinessEurope further emphasized that any review should be restricted to a possible amendment of the limit values and not touch any other provisions in the directives. They are also of view that the impact assessment scenarios already developed, are based on the limit value in one Member State, which is based on a different analytical model than those used in other Member States. They refer to the need of taking this into account when going forward since analytical models have an impact on the limit values set.

BusinessEurope mentioned the need to take into account the widely used protective measures. In addition, they referred to the additional costs and particular challenges for SMEs, a change of measurement method, as a result of a lower limit value would imply, i.e. additional analysis at workplaces, new requirements for PPE.

FIEC emphasized that the current EU legal framework is sufficient and does not support stricter occupational exposure limit values for the substances under consideration. They mentioned as well, that the European Commission's action should focus more on preventive measures to eliminate or minimise risks, rather than setting new binding limit values.

SMEunited underlined that before further tighten limits they would prefer a harmonised implementation of the existing OEL as for them, due to a very long delay of up to 40 years between exposure and occurrence of an asbestos-related disease it is difficult to assess the current OEL and the impact on the protection of workers.

Moreover, they added that reinforcing technical and financial assistance support for homeowners to assess the presence of asbestos in their dwellings before carrying out renovation works would contribute to the reduction of the exposure risk of construction workers.

Lead and its compounds

BusinessEurope referred to the voluntary agreements put in place by 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.

They also highlight the further protection provided by REACH, which not only restricts the use of lead and its compounds, but also includes obligations for training workers.

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

Diisocyanates

SMEunited is of view that a detailed analysis of the risks for diisocyanates justifying setting a limit value is missing. However, while in principle 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.

BusinessEurope, 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 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.

1.3 Consultations of scientists and stakeholders

The process of setting binding limit values under CAD and AWD actively engages the Member States and social partners during the key stages:

- Two stages consultation of the social partners at EU level in accordance with TFEU.
- External consultation on the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) before adoption.
- Development of opinions of the tri-partite ACSH via its Working Party Chemicals (WPC).

1.3.1 Scientific evaluation

An independent scientific assessment of the latest available scientific data is crucial for establishing new or revising the existing limit values.

The Commission sought advice from RAC, which delivered scientific assessments for lead and its compounds and for diisocyanates in September 2020. The scientific assessment on the health risks of asbestos exposure is expected by June 2021.

The scientific assessments will serve as the basis for proposals subject to impact assessment and social dialogue as well as tripartite consultation.

1.3.2 Consultation of Member States and Social Partners via the Advisory Committee on Safety and Health at Work

The ACSH is a tripartite body set up in 2003 by a Council Decision (2003/C 218/01) which is composed of three members per Member State, representing national governments, workers and employers' organisations. The ACSH is supported by tripartite working parties of experts on given topics.

The ACSH discusses adopted RAC opinions (and/or other appropriate scientific evidence) and adopts a formal opinion, which in the case of binding OELs also reflect other factors such as feasibility and socio-economic considerations.

An OEL emerging from this process reflects a deep technical, socioeconomic, and political consideration of what is achievable by employers across the EU and also ensures that workers' health is adequately protected.

Regarding asbestos, lead and its compounds and diisocyanates, the ACSH is expected to adopt opinions during its plenary meeting of December 2021.

2 PROBLEM DEFINITION

2.1 What is the problem and why is it a problem?

Asbestos

Asbestos is a highly dangerous carcinogenic agent. Airborne fibres are very resistant and when inhaled could lead to mesothelioma, lung cancer and other serious diseases.

As mentioned in the introduction, occupational cancer is the first cause of work-related deaths in the European Union, being primarily caused by exposures to carcinogenic substances such as asbestos, with other causes being, for example solar radiation and shift work. Occupational cancer is responsible for over 106 000 fatal cases per year in the EU-28[24]. Asbestos, for which there is no level of exposure below which the risk of asbestos-related disease can be eliminated, claims ~88 000 lives in Europe annually, accounting for 55-85% of lung cancers at work[7]. Mortality rates are estimated to continue to increase until the late 2020s and 2030s. Apart from the significant social and financial burden to those affected by the disease, including their families (in particular, due to long-term care), cancer is also associated with significant costs to society (e.g. loss of productivity, cost for social security systems). Recent estimations indicate that the cost of work-related cancers alone amounts to EUR 119.5 billion[25].

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

[25] EU-OSHA, The economics of OSH, 2017. Available at: https://visualisation.osha.europa.eu/osh-costs

There is no known safe exposure level to asbestos. The greater the exposure, the greater the risk of developing an asbestos-related disease. The time between exposure to asbestos and the first signs of disease can be as much as 30 years.

Although the use of asbestos is banned in the EU[26] there is a substantial legacy problem since it is still present in many older buildings that are likely to be renovated, adapted or demolished over the coming years. The exposure to asbestos is expected to increase due to the Renovation Wave initiative, part of the EU's Green Deal[27].

Taking into account conclusions of the ex-post evaluation concerning Asbestos at Work Directive[28] together with the disparities on the protection level among the Member States (see annex 1) and the evolution of the scientific knowledge, there is a clear indication for the need of an update of the actual provisions in the Directive.

Lead and its compounds

Lead and its compounds are key occupational reprotoxicants[29], which are responsible for around half of all exposure to reprotoxic substances at the workplace[30]. In addition to reproductive health problems, lead is also associated with neurological, renal, cardiovascular, haemopoietic[31], genotoxic[32] and carcinogenic effects[33]. Exposure to reprotoxic chemicals may lead to infertility, miscarriages or serious birth defects, amongst others.

Due to its properties and historical use, combined with its relative abundance and low cost, lead has been used extensively in construction, plumbing, battery production and the recycling industry. Given the well-recognised toxicity of lead, its uses have already been reduced or phased out for many applications. The preliminary analysis under the external study supporting the impact assessment predicts around 38 900 cases of adverse health effects over a period of 60 years, corresponding to 39% of the workforce.

The estimates show that between 27 and 1 274 new cases of reproductive ill health may occur each year, with lead and its compounds being the major contributor. The economic cost of reproductive ill health is estimated to be between €0.5 and €2.8 million per year in the best-case scenario. In a theoretical worst-case approach, estimation rises to €381 million per year.[34]

The main sectors for industrial production and use of lead and its compounds are primary and secondary lead production (incl. battery recycling); battery, lead sheet and

---

[26] The manufacture, placing on the market and use of asbestos is banned in the EU through REACH Regulation. Regulation (EC) No 1907/2006

[27] Energy efficiency in buildings – consultation on 'renovation wave' initiative. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12376-Commission-Communication-Renovation-wave-initiative-for-the-building-sector

[28] SWD (2017) 10 final.

[29] https://ec.europa.eu/social/main.jsp?catId=738&langId=en&pubId=8220&furtherPubs=yes

[30] https://op.europa.eu/en/publication-detail/-/publication/094387fb-da9a-11e9-9c4e-01aa75ed71a1

[31] Affects blood or blood cells.

[32] Damages the genetic information within a cell.

[33] ECHA Scientific report for evaluation of limit values for lead and its compounds at the workplace. https://echa.europa.eu/fr/oels-activity-list/-/substance-rev/22917/term

[34] Study on reprotoxic chemicals. https://ec.europa.eu/social/

ammunition production; production of lead oxides and frits; lead glass and ceramics production.

The EU binding OEL and BLV for lead and its compounds under the Chemical Agents Directive has not been updated for more than 20 years and therefore does not take into account the latest scientific and technical developments. In addition, limit values adopted at national level differ remarkably in Member States (see Annex I) leading to disparities in workers protection and differing operating conditions for business.

Diisocyanates

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

Diisocyanates are the most common group of isocyanates used at the workplace. They are highly reactive compounds and undergo rapid exothermic reactions with all kinds of nucleophiles[35]. Diisocyanates are widely used, for example, in the manufacture of polyurethane foams, plastics, coatings, varnish, two-pack paints and adhesives.

Preliminary data collected through consultation for the external study supporting the impact assessment[36] provides evidence of approximately 2,8 million workers currently exposed to diisocyanates, with the construction sector being the major contributor to this number. The first estimates point to 4 506 new cases of asthma per year and 16 180 new cases of irritation due to diisocyanates exposure. In the absence of an EU level OEL, different limit values have been established at a national level in certain EU Member States.

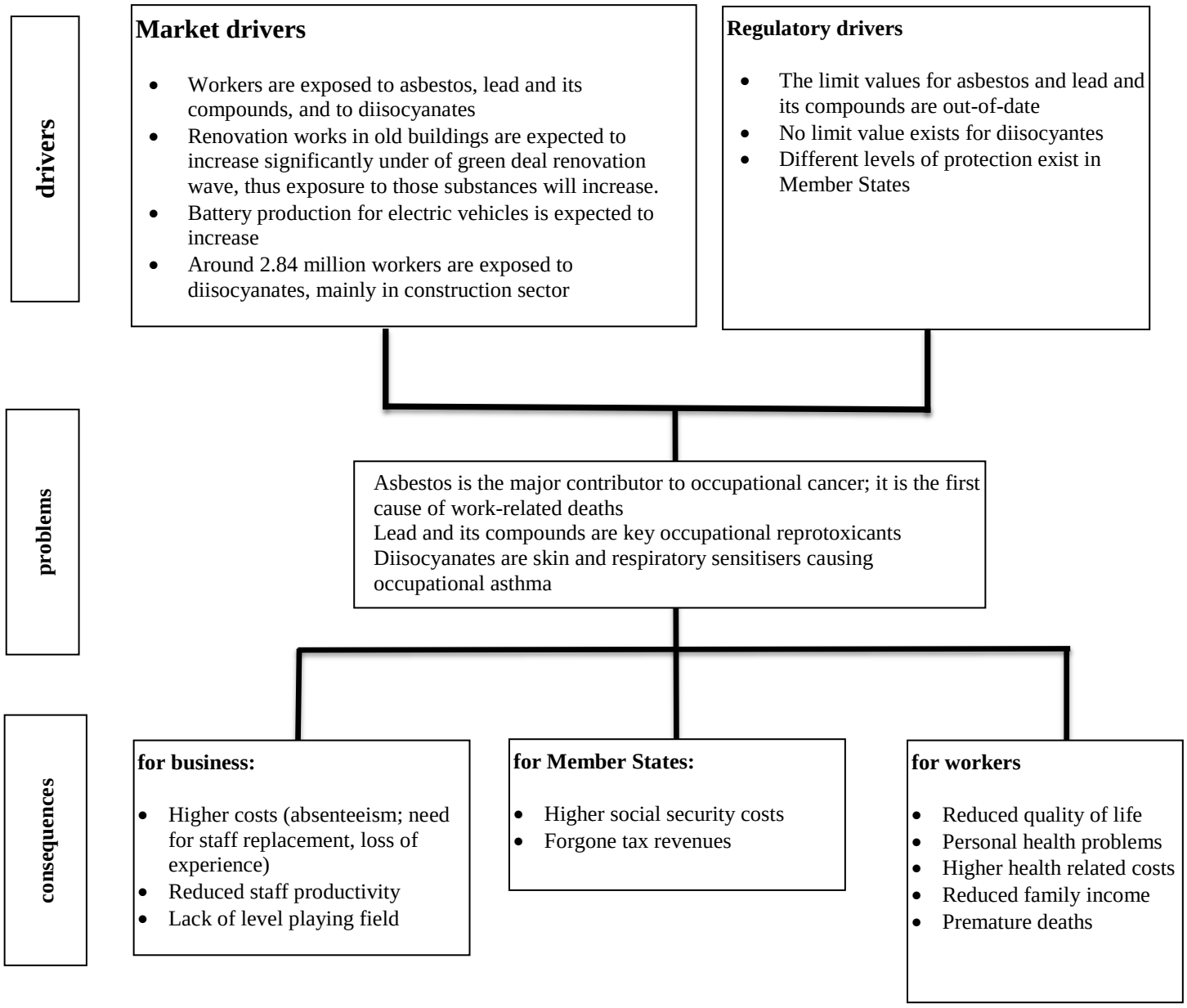
The below problem tree summarises the main drivers behind this problem and the resulting consequences for workers, business and Member States.

[35] Examples of nucleophiles are the halogen anions (I-, Cl-, Br-), the hydroxide ion (OH-), ammonia (NH3), and water (H2O)

[36] 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) - Interim report for diisocyanates

2.2 Market drivers

This section presents estimations of numbers of workers exposed to asbestos, lead and diisocyanates. In addition to estimates of occupational exposure, also the main adverse health effects are presented.



Asbestos

- **Occupational exposure**

Exposure to *in situ* asbestos in buildings and infrastructure materials and installations is assumed to be the main source of asbestos exposure today.[37]. The relevant route of occupational exposure is through inhalation[38].

The total number of occupationally exposed workers in Europe has been over 1.2 million during the period 1990-1993. The preliminary data analysis performed by the external study team estimates a total of 4 to 6 million of workers to be exposed to asbestos, with the major contribution (3,5 to 5,5 million) being from workers on situation of sporadic and low intensity exposure. The estimation of workers working in the building and construction sector with exposure situations subject to notification[39] is of 300 000 to 500 000 workers.

According to the Finnish database during the period of 2004 to 2015, the occupational limit value for asbestos, 0.1 fibres/cm3 was exceeded very rarely in situations other than inside the enclosed environment where asbestos removal work took place. In these situations, airborne concentrations could reach levels over 10 fibres/cm^3. The outlet air of these enclosed spaces and sometimes even inside respiratory protective equipment high exposures were measured[39].

- **Adverse health effects**

As already mentioned, asbestos is a well-known carcinogen, which may lead mesothelioma, lung cancer and other serious diseases.

The available data shows that exposure to asbestos fibres can result in mutagenic effects in vivo. In addition, there is some evidence indicating local genotoxic effects (damaging the genetic information within a cell causing mutations, which may lead to cancer). No in vivo studies are available to demonstrate a threshold for genotoxicity, furthermore the epidemiological data does not indicate existence of a threshold for cancer risk. Therefore, asbestos fibres should be considered as 'non-threshold' genotoxic carcinogens.

[37] 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) - Interim report for asbestos

[38] ECHA Scientific report for evaluation of limit value for asbestos at the workplace. Draft report dated of 01 February 2021

[39] Activities in which workers are or may be exposed in the course of their work to dust arising from asbestos or materials containing asbestos must be notified to national authorities. In case of sporadic and low-intensity worker exposure, and that the exposure limit for asbestos will not be exceeded in the air then notification may be waived.

Lead and its compounds

- **Occupational exposure**

Different sources provide varying data on the number of workers exposed to lead and its compounds.

Estimations by extrapolation of the Finish Biological monitoring (2012) data for EU values return a total of 373 000 workers exposed to lead and its compounds. The same exercise using the French SUMER database (2016/17) gives 1 350 000 workers exposed[40].

RPA[42] estimates that between 47 200 and 150 500 workers are potentially exposed at reported blood-lead levels. The number of female workers exposed to lead and its compounds is estimated between 2 680 and 10 543 while the number of workers of childbearing capacity is between 1 626 and 6 689.

Foundry and other similar processes are likely to generate the highest exposure levels.

- **Adverse health effects**

Exposure to lead and its compounds at the workplace occurs mainly through inhalation or ingestion, dermal uptake makes a negligible contribution to systemic lead levels.

Once taken up into the body, lead is not further metabolised. However, it will distribute to various tissue compartments such as blood, soft tissue and bone. The half-life of lead in the body varies depending on the body compartment; lead is retained far longer in bones, up to several decades[41]. During pregnancy, lead stored in bone may be remobilized into the blood, thus exposing the fetus.

Exposure to lead and its inorganic compounds have been shown to have diverse biological effects in humans, such as neurological, renal, cardiovascular, haemopoietic, reproductive, genotoxic and carcinogenic effects [43].

Diisocyanates

- **Occupational exposure**

According to the RAC opinion on diisocyanates[42], both inhalation and dermal exposure are likely and relevant routes for occupational exposure to diisocyanates. Both routes are relevant for induction of respiratory sensitisation, still contribution of dermal exposure to respiratory sensitisation cannot be quantified at present.

---

40 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) - Interim report for lead and its compounds

41 ECHA Scientific report for evaluation of limit values for lead and its compounds at the workplace. 17 October 2019

42 RAC opinion on diisocyanates

According the ECHA Restriction background document[43], the potential for occupational exposure to isocyanates is determined by several factors, such as volatility, hot processes, aerosolisation and dermal exposure.

The preliminary data collected through consultation for the external study supporting the impact assessment[44] provides evidence of approximately 2,8 million[45] workers currently exposed to diisocyanates, with the construction sector being the major contributor to this number.

Occupational exposure to diisocyanates is in particular possible during heating and spraying of isocyanates, during production of polyurethanes (e.g. slab-stock foam), handling of partly uncured polyurethane products (e.g. cutting, demoulding, spray application of foam), when isocyanates/PUs are heated (e.g. hot lamination, foundry applications/casting forms) and C.A.S.E. applications (coatings, adhesives, sealants, elastomers).

- **Adverse health effects**

The predominant health effects of occupational exposure to diisocyanates are irritation and sensitisation of the respiratory tract and skin, occurring both after acute- and long-term exposure.

The available evidence from human studies (epidemiological observational studies and challenge studies)[44] shows that diisocyanates exposure leads to respiratory effects including specific sensitisation, asthma, as well as accelerated lung function decline. Thus, respiratory effects, in particular occupational asthma and sensitization are the critical endpoints in case of diisocyanates exposure.

A threshold for bronchial hyper-responsiveness or for the development of asthma could not be observed, although theoretically sensitisation and elicitation are threshold phenomena. The threshold for developing sensitisation and asthma probably occurs at very low levels for which few observations exist.

2.3 Regulatory drivers

Asbestos under the Asbestos at Work Directive

Under the Asbestos at Work Directive, for all activities in which workers are or may be exposed to dust arising from asbestos or materials containing asbestos that exposure must be reduced to a minimum and in any case below the fixed binding limit value. The current value in the Directive is 0.1 fibres/cm^3.

[43] ECHA Restriction background document

[44] 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) - Interim report for diisocyanates

[45] These figures are all the first iteration of the analysis and are likely to change, possibly significantly

In addition, it is also stated that the minimum requirements of the Directive should be reviewed based on experience acquired and on technology developments in the relevant areas.

The general provisions of the Directive remain relevant. However, in the light of available scientific data there are grounds for considering the update of the current binding OEL.

Is expected that the RAC opinion, to be adopted in June 2021, does not recommend any health-based OEL as asbestos is a non-threshold carcinogen. Instead, it derives an exposure-risk relationship (ERR) expressing the excess risk for lung cancer and mesothelioma mortality (combined) related to different levels of exposure. It is also specified that the ERR was calculated for all types of asbestos, i.e. combining all studies regardless of the asbestos fibre type the population was exposed to and it focuses on air concentrations at and below the current OEL.

The cancer exposure-risk relationship proposed is:

Air concentration of asbestos (fibres/cm3) based on fibre measurements according to the Phase Contrast Microscopy method of WHO (1997) and combined information from study populations exposed to different asbestos fibre types	Excess life-time cancer risk (cases per 100 000 exposed)
0.001	1.2
0.002	2.5
0.005	6.2
0.01	12
0.02	25
0.05	62
0.1	125

The ACSH will prepare a draft opinion, proposing a binding OEL for asbestos, which will also take into account the economic feasibility, and socio-economic impacts.

In the EU Member States workers are subject to different levels of protection due to diverging OELs with some Member States having a stricter limit value for the protection of workers exposed to asbestos at work (0.01 fibres/cm³ and 0.002 fibres/cm³, while the current value in the Directive is 0.1 fibres/cm³). The list of national OELs is presented in Annex I.

Lead and its compounds and diisocyanates under the Chemical Agents Directive

According the Chemical Agents Directive, limit values shall be established or revised taking into account the latest available scientific data.

Lead and its compounds are currently the only substances in the Chemical Agents Directive to have a binding EU occupational and biological exposure limit value supplemented by a mandatory requirement for employers to undertake health surveillance. These values have not been updated for more than 20 years and therefore do not take into account the latest scientific and technical developments. The current binding

occupational limit value for inorganic lead and its compounds of 0.15 mg/m3 while the current binding biological limit value is 70 µg Pb/100 ml blood.

The RAC opinion, adopted in 11 June 2020, recommends an OEL of 4ug lead/m^3 (inhalable fraction) for lead and its compounds and a BLV equal to 150ug/L blood for lead and its inorganic compounds. RAC also recommends that special considerations should apply to women of childbearing age.

RAC does not propose limit values for organic lead compounds as in their view, due to limited old data and a lack of new data, no quantitative scientific evaluation was possible.

D**iisocyanates** are hazardous chemical agents in accordance with Article 2 (b) of Directive 98/24/EC and fall within the scope of the Directive. Currently, there is no EU OEL for diisocyanates.

RAC opinion states that 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[46]' could be obtained from the ERR for hyper responsiveness or diisocyanates asthma.

Excess risk over a working life period	Exposure - response relations derived from Pronk et al. (2009), and Collins et al. (2017), in µg/m3 NCO in air
0.1%	<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

It was further recommended a 15-minutes STEL that should be at maximum the double of the derived OEL based on the ERR and which should not exceed 6 µg/m^3 NCO.

In addition a skin sensitisation, respiratory sensitisation and `skin` notations where recommended.

The ACSH will prepare draft opinions for lead and its compounds and diisocyanates, proposing the limit values and notations, which will take into account the economic feasibility and socio-economic impacts.

[46] NCO is the functional group. All isocyanates are composed of one functional group while diisocyanates have two NCO groups.

3 CONSEQUENCES OF THE PROBLEM

3.1 Consequences for workers

Member States have introduced or revised national OELs for some, but not for all of the substances considered in this consultation. Where national OELs exist, they vary considerably, leading to different levels of protection of workers across the EU. The list of existing limit values (not be considered as exhaustive) is presented in Annex I.

A high exposure to carcinogens and hazardous chemicals has negative consequences for workers and their families across the EU.

For the workers and their families cancer and other health problems resulting from the exposure to asbestos and hazardous chemicals results in substantial losses of the quality and duration of their lives. Moreover, affected workers not only face considerable direct and indirect health care and rehabilitation costs, but also indirect loss of present and future earnings both for the person affected and for the carers. In addition, administration costs related to the time and expenses claiming for benefits, waiting for treatment, incur.

3.2 Consequences for businesses

For businesses, occupational diseases (cancer, asthma and other diseases) imply costs in terms of reduced productivity. Given the often-long time lag between exposure and illness and the probability of workers changing employers during their work career, the risk of future productivity losses is unlikely to be internalised by companies, and therefore not factored into present businesses' decisions. A study commissioned by the Commission (2011)[47] considers the socio-economic costs of accidents and ill health relating to work and the benefits to employers of implementing effective health and safety management policies. The report estimates that the cost to employers for a single case of a high-severity accident or disease is EUR 11 660. This figure is based on data pertaining to cost categories such as:

- reduced productivity of the injured employee after re-employment;
- costs of a replacement (difference in salary, reduced productivity);
- overtime of colleagues to compensate;
- rehabilitation costs (those paid by employer);
- medical costs (those paid by employer);
- administrative follow-up;
- reorganising the work; and
- training the replacement (time of the trainer).

As result of negotiations between employers and trade unions, some of the affected sectors/companies may also need to pay higher wages to compensate for the higher occupational risk.

[47] Full study report available at: http://ec.europa.eu/social/BlobServlet?docId=7416&langId=en

Finally, businesses located in Member States where national OELs are relatively stringent may be at a competitive disadvantage vis-à-vis enterprises in Member States with no or higher OELs. Thus, varying OELs negatively impact the functioning of the internal market by causing fragmentation from the adoption of possibly different rules at national level. Also the technological progress and innovation is less promoted.

Regarding OELs in countries outside the EU, an overview of OELs for asbestos, lead and its compounds and diisocyanates are provided in annex 2 of this document.

3.3 Consequences for Member States

Apart from the significant social and financial burden to those affected by cancer and other occupational diseases, including their families, the diseases are also associated with significant costs to society from coping with them. If national OEL exist, they vary considerably at present, and thus the consequences for Member States differ in their impact.

For Member States, occupational diseases lead to increased healthcare costs related to treatment and rehabilitation, as well as to higher expenditure on associated inactivity and early retirement and compensation for recognised occupational diseases. Work-related ill-health and injury are estimated by EU-OSHA to cost the EU about 476 billion euro a year (2017 figures), or around 3.3% of EU GDP. According to a recent report, direct costs of work-related cancer in terms of healthcare and productivity losses amount to at least to some EUR 4 – 7 billion per year; and the indirect costs may reach as much as EUR 334 billion each year.

Occupational diseases also increase administrative and legal costs related to the handling of requests for benefits and dealing with recognized cases. Foregone earnings and income as a result of ill health also lead to tax revenue losses for social security systems.

In addition, work-related illness also impacts the economy at large, reducing labour supply (either temporarily or permanently) not only by the person affected but also by his/her carers, decreasing labour productivity, and increasing the burden on public finances through avoidable public expenditure on health and long-term care, disability benefits, pensions for early retirement, and other benefits.

4 EU COMPETENCE AND EU ADDED VALUE

4.1 Necessity and EU added value

Updated scientific basis of prevention and protection

In order to ensure that the mechanisms for protecting workers from the risks related to exposure to asbestos, lead and diisocyanates established in the Asbestos at Work Directive and Chemical Agents Directive are as effective as possible, those Directives need to be kept up to date with scientific developments and technical progress.

Available scientific evidence points to the need to revise the limit values for asbestos and lead and its compounds and to establish new OELs for diisocyanates.

Updating Asbestos at Work Directive and Chemical Agents Directive to take account of newer scientific evidence is an effective way to ensure that preventive measures would be adjusted accordingly in all Member States.

Improved clarity and enforcement

Revising and /or establishing new limit values would provide a common reference point that can be used as a practical tool by employers, workers and enforcers to assess compliance with the general Directives requirements. Relevant and updated limit values are important for risk assessment and work planning and by process plant- and machinery designers when planning new production lines or considering alterations to existing process plants.

Ensuring the same minimum level of protection across the EU

Lack of EU action will most likely mean that the disparities on the workers protection among the different Member States will continue to exist or even increase, with several Member States not having a limit value for diisocyanates. A minimum standard across the EU will not be ensured, to the detriment of worker protection.

Contribution to level-playing field

National limit values vary considerably in some cases – leading to significantly different competing conditions. For asbestos, the values differ by a factor 200 among the different Member States, while for lead and its compounds, the lowest limit value is 3 times lower than the upper limit value. For diisocyanates, the situation is even more disperse with several Members States having introduced limit values for different types of diisocyanates with different values among them. For example, in the case of hexamethylene di-isocyanate (HDI) the OEL varies between 0.035 mg/m^3 and 1 mg/m^3 among eight countries where the limit is set.

This can have negative consequences for the internal market because businesses operating in Member States with less stringent levels or no exposure limit value at all (in the case of di-isocyanates) would benefit from an undue competitive advantage.

Revising or establishing EU limit values would not completely eliminate the national differences, as it sets only minimum standards and therefore Member States retain the possibility to adopt more protective measures. However, it could significantly minimise the scope for variation in limit values across the EU, as a majority of Member States in practice adopt the EU limit values directly.

4.2 Foundations of the right to act

Legal basis

The Treaty on the Functioning of the EU in Article 153 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.

The protection of workers' health against risks arising from exposure to carcinogenic and other hazardous chemicals substances is already covered by EU OSH legislation, in particular by the CAD and AWD, as well as under the REACH Regulation.

Amending the CAD and AWD can only be done by action at EU level.

4.3 Coherence with other relevant EU instruments/policies

4.3.1 Coherence with the 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. Ensuring a safe and healthy work environment is a strategic goal for the European Commission.[48]

4.3.2 Consistency and synergies with the REACH Regulation [49]

The REACH Regulation, adopted in 2006, consolidated and evolved several parts of the EU chemicals legislation – principally those relating to risk assessment and internal market risk management measures. The REACH Regulation established the 'registration' of all chemicals above 1 tonne on the EU market and 'authorisation' and 'restriction' as risk management measures to control the exposures of chemicals, including substances of very high concern (SVHC), at the workplace or for industrial uses.

Altogether, the Chemical Agents Directive, the Asbestos at Work Directive, the Carcinogens and Mutagens Directive and the REACH Regulation are relevant for worker protection for the majority of hazardous chemicals considered in this consultation.

A hazardous chemical may appear complementary in both sets of legislation, in the EU OSH chemicals legislation and the REACH Regulation Annex XIV (the list of SVHCs which can only be placed on the market or used if an authorisation has been granted for a specific use by the European Commission), as well as on the REACH Regulation Annex XVII (restricted substances).

The OSH Framework Directive – under which CAD, AWD and CMD are operational – applies without prejudice to existing or future national and EU provisions, which are more favourable to the safety and protection of the health of workers at work. The REACH Regulation in turn applies without prejudice to worker protection legislation, including the CAD, AWD and CMD.

---

[48] Communication from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020

[49] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

Clear synergies between the REACH Regulation and worker protection legislation exist – in particular, the REACH Regulation 'registration' should result in more information being available to inform chemicals risks assessment.

The REACH Regulation 'authorisation' and 'restrictions' also establishes, for a given chemical agent, a clear and renewed pressure to substitute it with safer alternatives, and can drive applicants to improve their risk management measures and operational conditions to improve worker protection. At the same time, EU OELs are recognised as useful inputs for the risk characterisation under the REACH Regulation.

An authorisation under the REACH Regulation may only be granted for specific uses and operators who have demonstrated that the risks are either adequately controlled (the 'adequate control route') or are lower than the socio-economic benefits derived from the use (the 'socio-economic route') and there are no suitable alternatives.

Workers exposure is the main exposure scenario today for almost all substances listed in Annex XIV as most of these chemicals are used in industrial settings.

Applicants for authorisation must include, amongst other elements, for each of the uses covered in their application, an assessment of the exposure of workers to the substance(s) and the related risk, at the individual workplaces concerned or over a representative sample of workplaces. If the risk management measures set out in the application are not judged to be appropriate and effective by ECHA's Risk Assessment Committee, conditions and/or monitoring arrangements can be imposed in the authorisation decision to reduce exposure and risks further, including biomonitoring and regular occupational exposure measurements.

However, some uses of substances are not covered by the authorisation requirement, namely intermediates[50] and unintended process generated substances.

Intermediates as defined by the REACH Regulation are chemical substances which are manufactured for and consumed in or used for chemical processing in order to be transformed into another substance[51]. Occupational exposure to intermediates may nevertheless occur for example during cleaning, maintenance, etc. where residues may be present and/or where process-streams are interrupted and containment may be compromised.

The co-existence of OELs under the EU OSH chemicals legislation alongside the REACH Regulation authorisation or restriction provides several important benefits for the practice of both OSH and the REACH Regulation worker protection provisions, as OELs apply to all potential worker exposures – including those associated with intermediates, and process-generated substances, or resulting from unintended or misuse-related release.

[50] Apart from 'non-isolated intermediates' which, during synthesis, are not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.

[51] Article 3(15) of REACH

For non-threshold carcinogens, as asbestos, the OEL provides a minimum standard exposure levels – ultimately passing through the co-legislator for adoption – based on a science and stakeholder consultation based process.

Status of the substances under the REACH Regulation

The applicable provisions of the REACH Regulation authorisation and/or restriction, where relevant, for the chemical agents under consideration, are as follows:

Asbestos

The manufacture, placing on the market and use of asbestos fibres and of articles and mixtures, containing these fibres added intentionally is prohibited under the REACH Regulation since 1983, with several amendments:

Name of agent in Annex XVII	Entry No.	Conditions of the restriction
Asbestos fibres	06	https://echa.europa.eu/documents/10162/ea9dc42d-7656-8afd-09e4-d8b41fae2c9c

Lead and its compounds

Lead and its compounds 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] is included in the SVHC listing since June 2018, as a substance toxic to reproduction.

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. A Commission Regulation was also

recently adopted amending Annex XVII to REACH and introducing detailed training requirements for workers[52].

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

5 POLICY OBJECTIVES AND AVENUES FOR EU ACTION

The main general policy objective of these initiatives is to ensure and maintain a high level of protection of workers' health and safety in the European Union.

The objectives of the Commission's work are more specifically:

- To further improve workers' protection from occupational exposure to hazardous chemicals in the European Union;
- To increase the effectiveness of the EU framework by considering current scientific expertise;
- To ensure more clarity, facilitate implementation, and contribute towards a better level playing field for economic operators by reducing divergences in national protection levels.

5.1 Possible avenues for EU action

The Commission is considering a range of possible measures:

(1) No EU action / baseline scenario

(2) Legislative action / amendment of the current Directives

(3) Guidance documents

These possibilities are not mutually exclusive, as guidance documents can be combined with legislative action.

The first possibility is that of no action at EU level. The other avenues for action will be assessed against this baseline scenario. The baseline takes into account how the problem would evolve, considering all relevant societal, economic and technical developments that would probably occur in the following decades.

[52]Commission Regulation (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards di-isocyanates, (OJ L 252, 4.8.2020, p. 24-27).

The second possible measure for consideration, legislative action, would revise or establish the binding limit values at the European Union level.

Proposing binding limit values would be based in the first place on the scientific evaluation provided by RAC on the individual substances as well as on the opinions delivered by the ACSH considering also socio-economic feasibility factors. These will feed into the impact assessment on a potential legislative initiative of the Commission.

The level of limit vales would be set to improve the protection of workers to the risks arising from exposure to those substances at work, thus contributing to the decrease of occupational cancer and other occupational diseases burden, taking into account the related costs that would accrue due to additional expenses for businesses.

The third possible avenue for EU action, guidance documents, is to revise existing ones and to develop brochures containing recommendations how to protect employees from exposure to the substances specified. The Commission could entrust the EU-OSHA to develop, for the use by national authorities and employers, guidance to good practice addressing these substances.

5.2 Impacts of possible avenues for EU action

The main benefits from lowering exposure levels accrue from a reduction of occupational cancer and other health problems among European workers. Cancer is the main cause of work-related death with over 106 000 fatal cases per year in the EU-28. Moreover, 815 DALYs (years of life lost and lived with disability) per 100 000 workers are caused yearly by work-related cancer in the EU-28. Following on from this, EU-OSHA estimates that the cost of work-related cancers alone amounts to EUR 119.5 billion in the European Union.

More information on the expected cases of cancer due to exposure to **asbestos** will be available with the conclusion of the external study supporting the impact assessment.

In the case of **lead and its compounds**, the preliminary analysis under the external study supporting the impact assessment predicts around 38 900 cases of adverse health effects over a period of 60 years and for a workforce of 98 850 . Effects on fertility are expected to be approximately 1239 cases while 7060 cases are estimated for developmental toxicity (effects on foetus).

Preliminary data on **diisocyanates** collected through consultation for the external study supporting the impact assessment indicates that over the last 60 years 270 357 cases of asthma and 970 812 cases of irritation were due to exposure to these substances. The predicted number of cases is 215,178 for asthma, and 970,812 for irritation over a 60-year period for a workforce of 78,729, with an associated cost of up to €9.9 billion for asthma and up to €680 million for irritation.

The positive as well as the negative impacts from a reduction in occupational exposure to hazardous chemicals depend on the specific exposure levels achieved, but also on determinants such as the number or workers exposed, the toxicity of the chemical and the market structure of the industries using those substances.

The three possible avenues for EU action are likely to differ in their effectiveness and impacts. Specifically, benefits would accrue for workers and their families, businesses and Member States, but also costs for businesses and workers could occur.

Table 1 gives and overview over potential impacts for the different avenues for EU action.

Table 1: Possible avenues for consideration and their impacts

Possible measures for consideration	Impacts			
	Social (including health)	Economic	Legislative	Environmental
1. No EU action / baseline scenario	Gaps in worker protection will persist. Significant costs in terms of avoidable deaths, suffering and healthcare.	The costs for businesses will continue to vary significantly between MS. No increased costs for businesses, but disadvantages in terms of productivity and competitiveness.	No legislative action required.	No significant impact expected.
2.Legislative actio n / amendment of the current Directives	Significant reduction in avoidable deaths, suffering and healthcare costs expected.	Costs for businesses regarding protective measures. Benefits from a healthier workforce.	Amendment of the CAD, AWD and CMD via ordinary legislative procedure.	No significant impact expected.
3. Guidance documents	Gaps in worker protection will persist. A possible reduction of some avoidable deaths and suffering, and healthcare costs.	Small voluntary costs for businesses. Disadvantages in terms of productivity and competitiveness will persist.	No legislative action required.	No significant impact expected.

Under **the first possibility**, the baseline scenario, the EU would not act. It is expected that a considerable amount of occupational cancer and other occupational diseases would continue to be caused by the exposure to hazardous chemicals covered by this document and that significant differences in national OELs would persist. Those non-avoided diseases would translate into significant health costs. For asbestos and lead and its compounds no improvement in workers protection would take place while for diisocyanates, worker protection would have to rely on REACH Regulation risk management measures. A study commissioned by the European Commission will look further into the costs and benefits that would occur under the baseline scenario.

Concerning **the second possible avenue**, the revision or establishment of binding limit values for hazardous chemicals covered by this document, this would require all companies to adhere to specified limit values, and thus very likely reduce the occupational cancer and other diseases burden. Moreover, standardisation of limit values for the specified substances would improve the functioning of the internal market by reducing further fragmentation from the adoption of different rules at national level. Although Member States are still free to choose more protective limit values, internal coherence will likely be increased. As limit values sets an objective to be achieved without being prescriptive in how this should be achieved, they can accommodate technical developments in the world of work such as new or enhanced processes. On the other hand, businesses will face increasing costs to comply with the limit values, including likely expenses for ventilation systems and personal protective equipment. The magnitude of the costs and benefits of possible limit values will depend on the specific limit value proposed.

Concerning **the third possible avenue**, guidance documents, it is voluntary for businesses to follow such advice. A general positive impact is expected from such an initiative, as some occupational diseases (i.e. cancer; ashma, etc) cases could be avoided by following best practice. However, there might be several reasons for this option not being effective, such as cost pressure on companies not to invest in OSH, the lack of knowledge about these guidance documents, or general lack of awareness about OSH best practice. Subsequently, it is likely that gaps in workers protection would persist, with a significant amount of occupational cancer and other occupational diseases caused. Also, no effects on the internal market or overall competitiveness are expected and diverging national limit values would be maintained.

For all possible avenues, no environmental impacts are expected, as the limit values only applies to exposure levels within the workplace. However, the increased protection of workers from the exposure to the substances in analysed are likely to lead to positive environmental impacts.

Table 2 specifies the possible benefits and costs for the three main stakeholder groups regarding a potential reduction in occupational exposure to hazardous chemicals covered by this document. These benefits accrue under all policy avenues if a reduction of occupational exposure is achieved, for example by following guidance documents, or by following legal provisions.

The commissioned study will, to the extent possible, further explore costs and benefits as well distributive effects, regarding the market structure and business composition, the characteristics of workers affected and the geographical scope of the industries affected for the substances included in the third wave.

Table 2: Expected impacts from a reduction in occupational exposure hazardous chemicals considered by this document

	Workers and their families	Businesses	Government/ Administration
Benefits	Longer and healthier lives: avoided cancer cases, avoided other adverse health effects	Higher labour productivity (reductions in absenteeism,	Lower healthcare/long-term care cost for treatment and rehabilitation

	(such as e.g. respiratory conditions, dermal conditions) and avoided deaths	production losses, production disturbances and higher employee motivation, better company image)	
	Avoided adverse effects on mental wellbeing	Reduced administrative and legal costs connected to ill or workers	Lower expenditure for early retirement, disability benefits and compensation for recognised occupational diseases
	Avoided loss of present and future income, for workers and informal carers	Reduction in sick leave payments, rehabilitation costs insurance contributions (and/or disability compensation)	Reduced administrative and legal costs related to dealing with recognized cases and benefit payments
	Avoided private direct and indirect medical costs, rehabilitation and long-term care costs	Reduced costs of replacement, overtime of colleagues to compensate, reorganising the work	Tax revenue loss of foregone earnings
	Avoided cost of time claiming benefits, waiting for treatment	Increased clarity and guidance as regards the application of the relevant provisions and avoided administrative and other burdens	Increase in labour supply by workers and caring relatives
	Reduction in insurance contributions in the long term	Incentives for innovation, leading to increased competitiveness	
Costs	Fewer employment opportunities, if businesses, potentially SMEs, are forced to close	Expenses for company and personal protective equipment	
		Changes in the production processes, cost of substitution by less hazardous substances	

5.3 Chemical agents under consideration

5.3.1 Asbestos

Asbestos is the generic commercial designation for a group of naturally occurring mineral silicate fibres of the serpentine and amphibole series. These include the serpentine mineral chrysotile ((also known as ´white asbestos´), and the five amphibole minerals – actinolite, amosite (´brown asbestos´), anthophyllite, crocidolite (blue asbestos) and tremolite[53][54]. Asbestos fibres possess high tensile strength, flexibility, resistance to chemical and thermal degradation, and high electrical resistance and can be woven. Asbestos was used worldwide in building and other materials in many areas of daily life. Although is no longer in use in the EU, there is a substantial legacy problem due to its presence in many older buildings that are likely to be renovated, adapted or demolished over the coming years.

5.3.2 Lead and its compounds

Lead and its compounds are used in 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. Other industrial applications are foundries and production of articles made of lead alloys, as well as production and use of pigments for paint and plastics.

ECHA notes that lead is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 000 tonnes per annum.

5.3.3 Diisocyanates

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 use of diisocyanates is widespread throughout the industry sector through use in paints, glues, greases, insulation, sealant; fibre bonding foundry cores; lacquers; finishes on synthetic floorings and other applications; soft and hard plastics, plastic foam and cellular plastic; inks and lacquers; adhesive, lacquers, upholstery stuffing and fabric coatings; synthetic textile fibres.

According to ECHA, for the 19 substances for diisocyanates considered registered under REACH, diisocyanates are manufactured and/or imported in the European Economic Area in 1000 - > 1 000 000 tonnes per year .[55]

[53] IARC (1973) Some inorganic and organometallic compounds. IARC Monogr EVal CArcinog Risk Chem Man, 2: 1-181.

[54] USGS 2001. Some Facts about Asbestos (USGS Fact Sheet FS-012–01), Reston, VA, US Geological Survey.

[55] ECHA (2021): Substance information Diisocyanates. Available at : https://echa.europa.eu/substance-information/-/substanceinfo/100.251.385

6 CONCLUSIONS

The analysis demonstrates that there is an important heterogeneity in the level of protection to workers among the different Member States for the substances considered in this document.

The continued establishment of new limit values, as well as the revision of existing ones, reflecting the latest available scientific evidence, is an effective way to ensure a minimum level of workers' protection in all Member States and would at the same time contribute to a level playing field.

This would also prevent cases when the values among Member States differ by orders of magnitude, leading not only to unequal workers protection, but also to complex socio-economic considerations for companies operating across the EU.

Revising existing values and establishing new limit values would provide a common reference point for employers, workers and labour inspectors enforcing the implementation of measures for workers protection improvement.

In the first phase consultation the social partners presented their views with regard to the revision and setting up of EU limit values. They agreed that binding limit values at EU level are beneficial for workers, businesses and the society in general.

ANNEX 1

Existing Occupational Exposure Limits (OELs) in EU Member States

Member State	Asbestos		Lead and inorganic compounds		Diisocyanates	
	TWA -8 hrs Fibres/cm3	Short term Fibres/cm3	TWA -8 hrs mg/m3	Short term mg/m3	TWA -8 hrs mg/m3	Short term mg/m3
European Union	0.1		0.15		-	
Austria	0.1	0.015	0.1 (I)	0.4 (I		
Belgium	0.1		0.15			
Bulgaria	0.1		0.15			
Croatia	0.1		0.15			
Cyprus	0.1		0.15			
Czechia	0.1		0.15			
Denmark	0.1	0.2	0.05 (I)	0.10 (I)		
Estonia	0.1		0.15			
Finland	0.1		0.1			
France	0.01		0.1 (I)			
Germany	0.1 (1) (2) 0.01 (3)	0.8 (2) (4)	0.15 (I) (BOELV) 0.1 (5)			
Greece	0.1		0.15			
Hungary	0.1		0.15 (I) 0.05 (R)	0.6 (I) 0.2 (R)		
Ireland	0.1		0.15		0.02 (as NCO15)	0.07 (as NCO15)
Italy	0.1		0.15			
Latvia	0.1		0.005	0.01		
Lithuania	0.1		0.15			
Luxembourg	0.1		0.15			
Malta	0.1		0.15			
Netherlands	0.002					
Poland	0.1		0.05			
Portugal	0.1					
Romania	0.1		0.15			
Slovakia	0.1		0.15			
Spain	0.1		0.15 (I)			
Sweden	0.1		0.1 (I) 0.05 (R)		0.002 ppm	0.005 (5 minutes average)

(1) BOEL
(2) Workplace exposure concentration corresponding to the proposed tolerable cancer risk
(3) Workplace exposure concentration corresponding to the proposed preliminary acceptable cancer risk
(4) 15 minutes average value
(5) Reference value that represents the state of the art. Individual measures are related to this LV.
(I) Inhalable fraction
(R) Respirable fraction

Lead - Biologic values (OELs) in EU Member States

Country/ Organisation	**Lead in blood**
European Union	70 µg Pb/100 ml blood
France (ANSES, 2017b)	180 µg/L
Finland	1.4 µmol/L (290 µg/L)
Germany (TRGS 903, 28.03.2019)	400 µg lead/L blood (for women older than 45 years and for men) 100 µg lead/L blood (for women younger than 45 years)
AGS, 2017	150 µg/L blood (not valid for women in childbearing age

ANNEX 2

Exposure limit values outside of the European Union

	UK	Australia	Canada	China	Japan	New Zealand	South Korea	Switzer-land	USA
Asbestos **f/cm^3**	**0.1**	**0.1**	Ontario: 0.1 Quebec: 1 (actinolite, anthophyllite, chrysotile, tremolite) 0.2 (amosite, crocidolite)	0.8 Inhalable fraction	0.15 (MHLW) 0.03 (JSOH) (1) 0.003 (JSOH)(2)		0.1	0.01	0.1 (NIOSH)
Lead and inorganic compounds mg/m3	**0.15**	**0.05**	0.05	0.05 (I) 0.03 (R)	0.05 (MHLW)	0.05	0.05	0.1 (I)	0.05
Diisocyanates						0.02			

(1) Individual excess lifetime risk of cancer 10^-3
(2) Individual excess lifetime risk of cancer 10^-4. except chrysotile

ANNEX 3 – LIST OF ACRONYMS

ACSH	Advisory Committee on Safety and Health at Work
CLP	Classification, Labelling and Packaging Regulation (EC) 1272/2008
CMD	Carcinogens and Mutagens Directive
ECHA	European Chemicals Agency
EFBWW	European Federation of Building and Woodworkers
ETUC	European Trade Union Confederation
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
IARC	International Agency for Research on Cancer
IOM	Institute of Occupational Medicine
NACE	**N**omenclature statistique des **a**ctivités économiques dans la **C**ommunauté **e**uropéenne (Statistical classification of economic activities in the European Community)
OELs	occupational exposure limit values
OSH	occupational safety and health
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) 1907/2006
RIVM	National Institute for Public Health and the Environment
SMEs	small and medium-sized enterprises
STEL	Short term exposure limit
TFEU	Treaty on the Functioning of the EU
TWa	Time-weighted average
UEAPME	European Association of Craft Small and Medium-sized Enterprises
WHO	World Health Organisation
WPC	Working Party on Chemicals