

June 2016

Exposure to carcinogens and mutagens at work

Main legal instrument:

Directive [2004/37](#) on the protection of workers from the risks related to carcinogens and mutagens at work

This briefing is one in a series of 'Implementation Appraisals' on the operation of existing EU legislation in practice. Each such briefing focuses on a specific EU law which is likely to be amended or reviewed, as foreseen in the European Commission's Annual Work Programme. Implementation Appraisals aim to provide a succinct overview of material publicly available on the implementation, application and effectiveness of an EU law to date – drawing on available input from the EU institutions and external organisations. They are provided to assist parliamentary committees in their consideration of the new proposals, once tabled.

EP committee responsible at time of adoption of the EU legislation:

– Committee on Employment and Social Affairs (EMPL)

Date of adoption of original legislation in plenary:

– 16 May 1990¹

Deadline for transposition of legislation:

– 31 December 1992 (Article 19 (1), Directive [90/394](#))

Planned date for review of legislation:

– Neither Directive 2004/37, nor Directive 90/394 include a review clause.

Timeline for new amending legislation:

– In the Commission Work Programme 2016 ([CWP 2016](#)), the European Commission presents its intention to review existing occupational health and safety legislation, including that on carcinogens and mutagens in the workplace. This review should 'improve the efficiency and effectiveness of an EU framework for protecting workers'. The European Commission proposed amendments to the existing legislation on 13 May 2016.

1. Background

According to [Eurostat](#), around 31 million tonnes of carcinogenic chemicals, mutagenic chemicals and chemicals toxic to reproduction (reprotoxic chemicals) are produced annually in Europe.² Exposure to these substances can have a serious negative impact on human health. In the workplace this exposure can considerably increase the risk of occupational diseases, including occupational cancers i.e. cancers attributable to working conditions. According to the European Commission, at least 20 million workers in the European Union are to a certain extent exposed to carcinogens in their workplace.³ It has been

¹ Directive 2004/37 consolidates and replaces Directive 90/394 and its amendments, without making any substantive changes. As such, Directive 2004/37 does not change the transposition dates of the original legislation.

² Carcinogenic chemicals can cause cancers, mutagenic chemicals can lead to genetic mutations, and reprotoxic chemicals can damage human reproductive processes.

³ [Inception Impact Assessment](#) on the legislative initiative to amend Directive 2004/37 on the protection of workers from the risks related to carcinogens and mutagens at work (April 2016).

estimated that in 2013 there were over 1 314 million cancer deaths in the EU.⁴ Worldwide, research by the International Labour Organisation in 2014 indicated that annually there are around 666 000 deaths related to occupational cancers.⁵ It was also estimated that in 2015 there were approximately 102 500 cancer-related deaths in the European Union.⁶ The most common type of occupational cancer is lung cancer, which is estimated at between 54 and 75% of all occupational cancers, with asbestos described as the major cause of this type of cancer (approximately 45%).⁷

1.1 Overview of legal rules

European legislation sets rules for exposure to and manipulation of chemicals and for the protection of human health. A high level of protection of human health and the environment with regard to exposure to chemicals is one of the objectives of the [REACH Regulation](#) 1907/2006 that sets out a general framework for chemical manufacturing and use across the EU. The REACH Regulation however does not deal with specific situations of prevention of exposure to these substances in the workplace. The general legal framework linked with safety and health in the workplace is established by [Directive 89/391](#), which introduces measures to encourage improvements in safety and health of workers at work.⁸ Specific rules dealing with the protection of workers from risks related to carcinogens and mutagens are included in Directive 2004/37, the main subject of this implementation appraisal. Despite wide-ranging European legislation, not all of the substances that can potentially increase the risk of occupational cancers are covered by the existing rules and thus the law needs to react to the newest scientific data.

There are several European agencies and bodies that are active in the existing framework of occupational safety and health protection and chemicals. These agencies include the [European Agency for Safety and Health at Work](#) (OSHA), the [European Foundation for the Improvement of Living and Working Conditions](#) and the [European Chemicals Agency](#) (ECHA) which is a European regulatory authority working on the safety of chemicals. Furthermore, various international bodies created under the auspices of the United Nations, such as the [World Health Organization](#) (WHO),⁹ the [International Labour Organization](#) (ILO) and the [International Agency for Research on Cancer](#) (IARC), deal with occupational safety and health and/or prevention of cancer.

Directive [2004/37](#) on the protection of workers from the risks related to carcinogens and mutagens at work

Directive 2004/37 consolidates and replaces Directive 90/394 and its amendments. The directive was amended in [2014](#). Its aim is to protect health and safety in the workplace by establishing specific requirements for the protection of workers who either are or are likely to be exposed to *carcinogens and mutagens*. In this context, the directive defines minimum requirements, including permissible occupational exposure limit values and various preventive measures. The directive is not applicable to workers exposed to radiation, who are covered by the [Euratom Treaty](#).

In its definition of mutagens and carcinogens, the directive refers to Regulation [1272/2008](#) on classification, labelling and packaging of substances and mixtures.¹⁰ Mutagens and carcinogens are defined as various substances or mixtures of substances that meet the criteria for classification as a category 1A or 1B carcinogen/mutagen set out in Annex I to Regulation 1272/2008.¹¹

⁴ J. Takala, [Working paper](#) - Eliminating occupational cancer in Europe and globally (2015), p. 6.

⁵ N. Nenonen et al., [Global estimates of occupational accidents and fatal work-related diseases in 2014](#), Singapore, Workplace Safety & Health Institute (2014), p. 1.

⁶ J. Takala, Working paper - Eliminating occupational cancer in Europe and globally (2015), p. 6.

⁷ *ibid.*

⁸ Article 1 (1) Directive 89/391.

⁹ For example, WHO has [classified](#) 107 agents, mixtures, and exposure situations as carcinogenic to humans.

¹⁰ This regulation includes a list of classifications of Category 1 carcinogens which contains 1 017 chemical substances (Annex IV, Regulation 1272/2008). These substances must carry a label stating 'may cause cancer' (Article 13b, Regulation 1272/2008).

¹¹ These criteria are set in Point 3.6.2. of Annex I for carcinogens and Point 3.5.2. of Annex I for mutagens.

Under the directive employers are obliged to:

- (1) reduce the use of carcinogens and mutagens at the place of work and replace them with substances that are not dangerous or that are less dangerous (Article 4);
- (2) prevent or decrease exposure to these substances (Article 5). In this context, Annex III of the directive sets obligatory exposure limit values;
- (3) inform the competent authority of activities including the substances used, their quantities, the number of exposed workers, preventive measures and replacements, etc. (Article 6);
- (4) inform workers in the event of an unforeseeable event or an accident that is likely to result in abnormal exposure (Article 7);
- (5) limit exposure of workers to these substances in cases of foreseeable exposure, such as maintenance (Article 8);
- (6) restrict access to risk areas to those workers who by reason of their work duties have to enter them (Article 9);
- (7) take measures ensuring hygiene at the workplace and provide workers with protective clothing (Article 10);
- (8) provide workers with training, for example, on potential health risks, precautions and protective equipment (Article 11).

The annexes to the directive include additional information: Annex I includes a list of substances, preparations and processes; Annex II includes practical recommendations for the health surveillance of workers and Annex III contains a list of limit values for occupational exposure. However, at the moment, the annexes are rather short and limited as Annex I includes only five substances and processes, while Annex III contains exposure limit values only for three chemical substances (benzene, vinyl chloride monomer and hardwood dusts).

[Proposal for a directive](#) amending Directive 2004/37 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (13 May 2016)¹²

The goal of the proposal is to improve the occupational safety and health of workers by 'reducing occupational exposure to carcinogenic chemical agents, to increase the effectiveness of the EU legislation in this area and to provide more clarity and a better level playing field for economic operators'.¹³ The proposal revises and/or introduces exposure limit values for 13 chemical substances. Here the Commission intends to introduce three specific measures, namely to:

- broaden Annex I to include 'work involving exposure to respirable crystalline silica dust generated' and establish an exposure limit value for this carcinogen in Annex III;
- include exposure limit values for 10 additional carcinogens in Annex III and
- revise the existing exposure limit values for hardwood dusts and vinyl chloride monomer with regard to the newest scientific data.¹⁴

The proposal is supported by the European Commission [Impact Assessment](#).¹⁵ The impact assessment looks at the cost and benefits of broadening Directive 2004/37 which introduces exposure limit values for 13 chemical substances. The Commission claims that it wants to carry out an additional analysis for another 12 substances that it intends to present in a further impact assessment.¹⁶ The impact assessment estimates that by the year 2069, around 99 000 deaths related to respirable crystalline silica could be avoided. The adoption of the proposal should also prevent unnecessary health costs, which can range from EUR 34 to 89 billion for a given substance. In terms of hardwood dust the savings of these costs range from EUR 12 to 54

¹² COM(2016) 248 final.

¹³ Explanatory Memorandum to the proposal, p. 2.

¹⁴ *ibid.*, pp. 3 - 4.

¹⁵ SWD(2016) 152 final. For additional information on the impact assessment, please see the upcoming Briefing by the EPRS Ex-Ante Impact Assessment Unit.

¹⁶ *ibid.*, p. 8.

million.¹⁷ The impact assessment notes that businesses may incur operating costs linked with putting into place additional protective and preventive measures, in particular regarding Chromium (VI) compounds and respirable crystalline silica. The total costs to industry for setting occupational exposure limits for respirable crystalline silica are estimated at EUR 3.5 billion until 2069, while costs with regard to the other 12 substances are minimal.¹⁸ The proposal has an impact on SMEs as they are not exonerated from the obligations included in the proposal.

2. EU-level reports, evaluations and studies

European Commission [Inception Impact Assessment](#) on the legislative initiative to amend Directive 2004/37 on the protection of workers from the risks related to carcinogens and mutagens at work (April 2016)

The inception impact assessment¹⁹ notes that there needs to be a substantial improvement of Directive 2004/37 in order to reduce occupational exposure to carcinogens and mutagens. The document states that the Commission plans to amend Directive 2004/37 in a two-step procedure with the aim of extending the scope of the directive with regard to certain substances. As a first step the Commission intends to extend the scope of the directive to additional substances that are recognised as carcinogens outside the EU, so called process-generated substances.²⁰ In this step the Commission aims to extend the list of substances included in Annex III. The second step is expected to further broaden the scope of the directive to additional substances and establish occupational exposure limit values (OELs) for substances for which there is currently only limited data. The second step is linked with the results of the pending studies.

Furthermore, the inception impact assessment points to the REACH Regulation noting that REACH is complimentary to occupational safety and health legislation, particularly Directive 2004/37, and that it will be taken into account as it deals with certain substances that are or will be covered by restrictions or authorisations.

Three main problems are identified in the inception impact assessment: (1) a significant exposure of workers to carcinogens, (2) an outdated Directive 2004/37 and (3) the lack of occupational exposure limit values, which has a negative impact on workers and businesses in the EU.²¹ The inception impact assessment underlines that there are various substances and their mixtures not included in Directive 2004/37 although according to existing studies exposure to them can have a serious impact on human health. Because of these problems, the document calls for action at EU level. In this regard, it points to varying national limit values often based on differing methodologies or different data resulting in varying levels of occupational safety and health protection across the EU.

The main policy objective of this legislative initiative is 'to ensure and maintain a high level of protection of workers' health and safety in the European Union'. There are also specific objectives that include (1) the reduction of exposure to carcinogens and mutagens, (2) the increase of the effectiveness of EU legislation in that field and (3) more balanced protection against carcinogens in the workplace.

¹⁷ *ibid.*, pp. 78–79.

¹⁸ *ibid.*, p. 80.

¹⁹ The [Better Regulation Guidelines](#) (SWD (2015) 111 final) describe the 'inception impact assessment' as a roadmap for initiatives subject to an impact assessment. It sets out in greater detail the description of the problem, issues related to subsidiarity, the policy objectives and options as well as the likely impacts of each option.

²⁰ Inception Impact Assessment, p. 2.

²¹ *ibid.*, pp. 2-4.

European Commission [Communication](#) on the EU Strategic Framework on Health and Safety at Work 2014–2020²²

The Strategic Framework has several key strategic objectives, including an objective to address prevention of work-related and occupational diseases.²³ The Strategic Framework describes the main common challenges, which include: improving the implementation of existing operational security and health legislation in the EU, improving the prevention of occupational diseases and tackling demographic changes.²⁴ In order to respond to these challenges, the Commission proposes seven key strategic actions and objectives that need to be implemented by means of cooperation between the Member States, social partners and other stakeholders. The key strategic objectives are the following:

- consolidation of national strategies,
- facilitation of compliance with occupational safety and health legislation,
- better enforcement of occupational safety and health legislation,
- simplification of existing EU occupational safety and health legislation,
- addressing the ageing of the workforce, new risks, prevention of work-related and occupational diseases,
- improvement of data collection and
- better coordination of efforts to address occupational safety and health issues.²⁵

Despite setting the key strategy objectives and acknowledging the main common challenges, the Strategic Framework remains silent on the revision of existing European legislation on the protection of workers from the risks related to carcinogens and mutagens at work.

European Agency for Safety and Health at Work [European Risk Observatory Report](#) – Exposure to carcinogens and work-related cancer: a review of assessment methods (2014)

The report describes occupational exposure to carcinogens and contributes to the discussion on the prevention of occupational cancers. At the same time it points at various prevention measures, assessing the available data and making some recommendations in order to decrease occupational cancer risks. The report assesses various factors and different types of exposure that can have a negative impact on human health and increase risk of occupational cancers. More specifically, it addresses vulnerable groups of workers such as women, young workers or workers in precarious conditions. The report argues that only a limited number of potentially cancer-causing chemicals have been researched. It also highlights the fact that occupational exposure is only one of the factors causing cancer. The report provides several recommendations to:

- (1) design a return to work for those affected by cancer,
- (2) improve existing exposure assessment schemes by setting up a register for all Member States enabling wide data collection,
- (3) improve integration between the REACH Regulation and occupational safety and health legislation,
- (4) improve use of available data by the Member States,
- (5) improve prevention and control mechanisms in the workplace, and
- (6) minimise risk and improve implementation of the precautionary principle.²⁶

²² COM(2014) 332 final.

²³ *ibid.*, p. 10.

²⁴ *ibid.*, pp. 5–7.

²⁵ *ibid.*, pp. 7–12.

²⁶ European Risk Observatory Report, pp. 134-140. With regard to the precautionary principle please see also the EPRS [In-depth analysis](#) on the subject (2015).

European Commission [report](#) on the health, socio-economic and environmental aspects of possible amendments to Directive 2004/37 on the protection of workers from the risks related to exposure to carcinogens and mutagens at work (2011)²⁷

The report provides an analysis of the impact of broadening Directive 2004/37 to include 25 occupational carcinogenic substances²⁸ identified by the European Commission (DG Employment).²⁹ The results included in the report note that 11 of the above-mentioned 25 substances are identified as human carcinogens, four substances are considered probable human carcinogens and the remaining ten substances are characterised as possible human carcinogens.³⁰ The report points out that there are more than 10 different types of cancer that may be caused by exposure to these substances, including lung and bladder cancer.³¹ Furthermore, the report highlights that the three substances of concern to the greatest number of workers are benzo(a)pyrene (around 7 million workers), diesel engine exhaust (around 3.6 million workers) and hardwood dust (around 3 million workers).³² It also estimates that within a period of 60 years, if no action is taken, there will be more than 700 000 cancer deaths, while around 470 000 deaths are linked to exposure to respirable crystalline silica and around 270 000 deaths are linked to exposure to diesel engine exhaust.³³ The baseline health costs for the next 60 years associated with cancer treatment are estimated to be above EUR 1 000 million for the substances accepted as human carcinogens. The report notes that in only seven cases out of 44 combinations assessed were there considerable health benefits if occupational exposure limits were introduced.³⁴ The report calls for the proactive collection of information about occupational carcinogens throughout the EU. The report also includes an evaluation of the requirements included in Article 5 of Directive 2004/37 dealing with prevention and reduction of exposure to carcinogens and mutagens at the workplace. In this context, it notes that the elimination or substitution of carcinogens with an alternative is not always straightforward and might be difficult for SMEs to implement.³⁵

3. Stakeholder reports

H. Wriedt, Occupational Health & Safety Advice Centre, [Report](#) – Carcinogens that should be subject to binding limits on workers' exposure (2016)

This report identifies more than 50 carcinogens that should be covered by binding occupational exposure limits under Annex III of Directive 2004/37. The report also reflects on the regulatory value of the occupational exposure limits. Furthermore, the report considers additional carcinogens to be included in Annex IV of Directive 2004/37. It also considers several substances that can be characterised as 'future or potential' carcinogens when certain conditions are met.

T. Musu, L. Vogel, H. Wriedt, [Working paper](#) - Cancer risks in the workplace: better regulation, stronger protection (2016)

This working paper notes that the revision of Directive 2004/37 has been on the agenda for more than 12 years, as the objective stemmed from the [Community strategy for health at work for the period 2002 - 2006](#) when the Commission promised to propose an extension of the scope of the directive's predecessor. Furthermore, the paper calls for a more proactive, less reactive approach. According to the paper, the

²⁷ The study was outsourced by the European Commission's DG Employment and carried out in 2011 by the Institute of Occupational Medicine ([IOM](#)).

²⁸ These substances include, for example, hard wood dust, vinyl chloride monomer, trichloroethylene, beryllium and its compounds, chrome VI, acrylamide, rubber process fume, respirable crystalline silica, ethylene oxide, hydrazine, o-toluidine.

²⁹ These substances include, for example, hard wood dust, vinyl chloride monomer, trichloroethylene, beryllium and its compounds, chrome VI, acrylamide, rubber process fume, respirable crystalline silica, ethylene oxide, hydrazine, o-toluidine.

³⁰ IOM Report, p. 145.

³¹ *ibid.*, p. 37.

³² *ibid.*, pp. 36, 45 and 126.

³³ *ibid.*, p. 160, Table 8.5.

³⁴ *ibid.*, p. 1.

³⁵ *ibid.*, p. 164.

scope of Directive 2004/37 should be extended and aligned with the scope of the REACH Regulation. The directive should also be adapted so that it reflects the current state of scientific knowledge. In this regard, the directive and its annexes should be broadened to include additional process-generated substances such as crystalline silica, diesel engine exhaust emissions, rubber process dusts and fumes and used engine oils. The paper also lists 20 carcinogenic substances for which binding occupational exposure limits should be adopted.

J. Takala, [Working paper](#) – Eliminating occupational cancer in Europe and globally (2015)

The working paper calls for a stronger policy which would lead to the elimination of occupational cancer via gradual reduction of occupational exposure to carcinogenic substances. It notes that cancer-related deaths are estimated at 53% of all work-related deaths in the EU. According to the paper, in 2011 there were more than 102 500 occupational cancer-related deaths in the EU. The highest number of occupational cancer-related deaths occurred in Germany, followed by the UK and France. The working paper also points specifically to exposure to asbestos as it is linked with the highest number of work-related deaths from cancer as it causes between 30 000 and 47 000 deaths per year.³⁶ The paper calls for the launch of an international programme on the elimination of occupational cancer, to follow the approach adopted in the WHO [smallpox eradication programme](#). According to the paper the EU must play the main role in such a programme. In this context the paper requires 'full implementation of the REACH programme prioritising substitution of carcinogenic, mutagenic and reprotoxic substances in the authorisation and restriction processes'.³⁷ The paper also calls for revision of the relevant European legislation in order 'to set binding occupational exposure limits and ensure enforcement related to exposure to specific carcinogens, such as crystalline silica, diesel exhaust emissions and wood dust'.³⁸

4. European Parliament position / MEP questions

4.1 Resolutions of the European Parliament

European Parliament [resolution](#) of 25 November 2015 on the EU Strategic Framework on Health and Safety at Work 2014–2020³⁹

The European Parliament called for the prevention of work-related diseases. In this context it highlighted the importance of protecting workers against carcinogens, mutagens and reprotoxic substances. Parliament paid special attention to female workers. Furthermore, it called on the Commission to present a proposal to revise Directive 2004/37. The Commission was called upon in particular to add more binding occupational exposure limit values. It was also asked to address 'regulatory overlaps resulting in unintended non-compliance'. The Commission was also urged to pay attention to the issue of work-related cancers. Parliament here pointed to nasal-cavity tumours in cases where the protection of workers' respiratory systems was insufficient against common types of dust when processing wood, leather, flour, etc.

In its [follow up](#)⁴⁰ the Commission stated that in 2016 it intended to submit a proposal for an amendment of Directive 2004/37. The aim of the amended directive would be to 'enhance the protection of workers' health, in particular from work-related cancers resulting from exposure to chemicals'. Furthermore, the Commission pointed to three opinions of the [Advisory Committee on Health and Safety at Work](#) from 2012 and 2013, which also proposed binding exposure limit values.

European Parliament [resolution](#) of 12 September 2013 on the European strategy on health and safety at work⁴¹

The Commission was called upon to present European strategy on health and safety at work 2013–2020 before end of 2013. Parliament expressed its regrets about the Commission's decision not to present a

³⁶ J. Takala, Working paper - Eliminating occupational cancer in Europe and globally (2015), p. 6.

³⁷ *ibid.*, p. 17.

³⁸ *ibid.*

³⁹ P8_TA-PROV(2015)0411.

⁴⁰ SP(2016)105.

⁴¹ P7_TA(2013)0385.

review of Directive 2004/37 although this initiative had already been announced in the Commission's 2011 Work Programme.

The Commission's [follow up](#)⁴² to this resolution noted in the context of the review of Directive 2004/37 that the Commission was 'developing the assessment on the costs and benefits and other impacts of various policy options in order to address recent developments in this policy area'. The Commission intended to have this assessment ready before the end of its mandate in 2014.⁴³

European Parliament [resolution](#) of 14 March 2013 on asbestos-related occupational health threats and prospects for abolishing all existing asbestos⁴⁴

Apart from making calls to abolish the use of asbestos and pointing to asbestos-related occupational health threats and risks, Parliament urged the Commission to submit a proposal amending Directive 2004/37. Parliament intended by means of this amendment of the directive to secure the protection of workers' health 'through the promotion and exchange of best practices in prevention and diagnosis'. It also called on the Member States to ensure that asbestos-related diseases were recognised as occupational diseases.⁴⁵

European Parliament [resolution](#) of 10 April 2008 on combating cancer in the enlarged European Union⁴⁶

Parliament called on the Commission to set up an EU Cancer Task Force, which would be composed of representatives of the Commission, Council and Parliament which should meet regularly and collect practices for the prevention and treatment of cancer in Europe. The Commission was called upon to take legislative action in order to prevent cancer through the 'reduction of occupational and environmental exposure to carcinogens and other substances contributing to the development of cancer and promotion of healthy lifestyles'. Parliament pointed to various risk factors including tobacco, alcohol, obesity and sun protection. The Commission and ECHA were asked to publish a list of carcinogenic substances, to be accessible to consumers. In addition, the Commission was asked to draw up a charter for the protection of cancer patients and chronically sick people in the workplace, requiring the companies 'to enable patients to continue in employment during their treatment and to return to their normal professional activities'.

The Commission reacted to this resolution in its [follow up](#) document, acknowledging the Parliament's suggestion to establish an advisory committee on cancer prevention.⁴⁷ However, it noted that it had considered the need for this body in the 2009 [action plan](#). The Commission explained that the requested actions on occupational health protection were already highly regulated by European legislation and had already led to health risk reductions. Furthermore, it noted various actions of ECHA leading to recommendations on prevention of exposure to occupational carcinogens. With regard to the patients' charter, the Commission noted that this matter fell within the remit of the Member States.⁴⁸

4.2 Written questions of the MEPs

[Written question by a group of MEPs, 22 March 2016](#)

The MEPs asked the Commission when it intended to adopt binding European limit values for occupational exposure to the 50 main carcinogens that had been listed by the European Trade Union Confederation. The

⁴² SP(2013)816.

⁴³ No such assessment was adopted in 2014.

⁴⁴ P7_TA(2013)0093.

⁴⁵ The Commission in its follow up document ([SP\(2013\)442](#)) did not react to the Parliament's point calling for update of Directive 2004/37.

⁴⁶ P6_TA(2008)0121

⁴⁷ SP(2008)3164.

⁴⁸ Parliament adopted also other resolutions that dealt with the issue of occupational health and safety and to a limited extent also with carcinogens or mutagens in the workplace, such as: European Parliament [resolution](#) of 14 January 2014 on effective labour inspections as a strategy to improve working conditions in Europe; and European Parliament [legislative resolution](#) on the joint text approved by the Conciliation Committee for a European Parliament and Council decision adopting a programme of Community action in the field of public health (2003-2008).

MEPs also called upon the Commission to adopt these limit values by the end of 2016 and thus reduce the number of occupational cancer victims.⁴⁹

Written question by Kathleen Van Brempt (S&D, Belgium), 1 March 2016

The Commission was asked to inform the Parliament about its plans to introduce further regulation of exposure to hazardous substances at work. The MEP asked whether the Commission intended to give priority to regulation of 50 known carcinogens. Furthermore, the MEP inquired about the conclusions drawn from the evaluation of Directive 2004/37.⁵⁰

Written question by Holger Krahmer (S&D, Germany), 13 April 2011

The MEP asked the Commission whether it was aware of any industry concerns and arguments regarding the classification of gallium arsenide (GaAs). In this context the MEP inquired whether the Commission intended to re-open a public consultation for the classification of GaAs to cover reprotoxicity or if there were any reasons not to do it. A question about the method used by the Commission to assess this classification procedure was also asked.

Answer given by Mr Potočnik on behalf of the Commission, 10 May 2011

The Commissioner answered that he was aware of industry concerns regarding the GaAs's classification. In this context the Commissioner asked ECHA to initiate an additional public consultation so that stakeholders could comment on classifying GaAs as a carcinogen.

Written question by Nikolaos Chountis (GUE/NGL, Greece), 4 January 2011

The MEP asked whether the substance CS (2-chlorobenzylidene malononitrile) used by the Greek police to disperse demonstrations fell within the scope of Council Directive 98/24 and Directive 2004/37.

Answer given by Mr Andor on behalf of the Commission, 26 January 2011

The Commissioner informed the MEP that the substance mentioned was not a hazardous chemical agent according to Council Directive 98/24. Furthermore, he informed him that this substance did not fall within the scope of Directive 2004/37 as it was not classified as carcinogen or mutagen.

5. European Economic and Social Committee

The European Economic and Social Committee (EESC) has on several occasions produced opinions dealing with the issue of occupational security and health, and protection of workers against occupational cancers. The EESC has underlined the fact that occupational safety and health belong among the strategic priorities for the EU, with regard to the prevention of 'musculoskeletal disorders, long latency diseases and chronic conditions'.⁵¹ It has also noted the need for proper implementation of European legislation in this field. According to the EESC, the EU legislation must reflect the latest scientific and medical research results. In this context it highlighted the need to decrease the use of asbestos in the EU in and outside the workplace.⁵² The Committee also recommended extending the scope of Directive 2004/37 to include environmental tobacco smoke (i.e. passive smoking or second-hand smoke) which should be classified as a carcinogen.⁵³

6. Advisory Committee on Health and Safety at Work, Scientific Committee on Occupational Exposure Limits and Senior Labour Inspectors Committee

The Advisory Committee on Health and Safety at Work (ACHS) is an independent scientific body set up in 2003 by Council Decision [2003/C 218/01](#). The Scientific Committee on Occupational Exposure Limits

⁴⁹ At the time of drafting this briefing the Commission had not answered this question.

⁵⁰ At the time of drafting this briefing the Commission had not answered this question.

⁵¹ [Opinion](#) of 11 December 2014 on Health and Safety at Work – Strategic Framework 2014-2020, point 5.1.7.

⁵² [Opinion](#) of 20 February 2015 on Freeing the EU from asbestos.

⁵³ [Opinion](#) of 5 November 2009 on the Proposal for a Council Recommendation on smoke-free environments, point 1.3.

(SCOEL) was established by Council Decision [2014/113/EU](#)⁵⁴ and the Senior Labour Inspectors Committee (SLIC) was formally set up in 1995 by Commission Decision [95/319/EC](#). The task of the ACHS is to assist the Commission in the field of occupational safety and health, while SCOEL evaluates effects of chemical substances on the health of workers. SLIC gives its opinions with regard to enforcement of occupational safety and health provisions in Member States.

These bodies provide the Commission with opinions linked to occupational safety and health issues. For example, in its [opinion](#) on the protection of workers' health from risks arising from exposure to chemicals at the workplace (EU Occupational Exposure Limit Values under OSH and limit values under other EU legislation (2013)), the ACHS suggested that procedures under legislative systems such as REACH that are not exclusively dealing with occupational safety and health 'should not seek to set official EU limit values for worker protection'. In its [Supplementary opinion](#) No. 2 – on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37 on Carcinogens and Mutagens at the workplace (2013) – the ACHS agreed with the intention of the Commission to amend Directive 2004/37.⁵⁵ SLIC, in its 2012 [submission](#) on EU Strategic Priorities, 2013-2020, noted several priorities with regard to occupational cancer, including the proper functioning of the REACH Regulation and classification (of carcinogens etc.). It also adopted [guidance](#) for national labour inspectors on the interaction between the REACH Regulation and Directive 2004/37.

7. Stakeholder positions

The European Confederation of Trade Unions (ETUC) in its 2014 [resolution](#) called on the EU to act in order to improve occupational health and safety. It noted that more efforts in this field were required. The ETUC did not agree with the Strategic Framework 2014-2020 as it did not offer any real action. The ETUC called upon the Commission to provide clear guidelines for developing national strategies for occupational safety and health including in the area of prevention of occupational cancers. It also called the Commission to reformulate and transform the existing legislation on occupational safety and health 'into a modern, up-to-date framework'. After amendments to Directive 2004/37 were proposed by the Commission, the ETUC issued a [press release](#) in which it noted that the proposal was 'a significant step forward'. However, at the same time it argued that some of the exposure limits were inadequate and that some substances were not included in the proposal. It also called upon the Commission to 'put forward the exposure limits for at least 15 more substances by the end of the year'. The European Trade Union Institute (ETUI) also welcomed the revision of Directive 2004/37 and the new Commission proposal. However, it [described](#) this initiative as 'only a small step forward'.

The representative of the national businesses federations, BUSINESSEUROPE noted in its 2014 [position paper](#) that there was already a 'body of EU legislation protecting workers from risks which can cause work-related diseases, including exposure to chemicals, carcinogens and mutagens'. In this regard, it expressed its belief that the focus should now be on the implementation of the existing legislation and not adopting additional new legislation. BUSINESSEUROPE also noted that some issues relating to occupational safety and health were not best dealt with by binding legislation. Nevertheless, it underlined a need for businesses to 'put in place effective and efficient risk prevention measures.' The European Association of Craft, Small and Medium-sized Enterprises (UAPME) meanwhile noted in its 2014 [position paper](#) that it was necessary to focus on simplification of existing legislation and improvement of prevention of work-related

⁵⁴ The SCOEL was established by Commission Decision 95/320/EC, however this decision was repealed by Council Decision 2014/113/EU.

⁵⁵ The ACHS also adopted other opinions reacting to occupational exposure values, for example, its [opinion](#) on the preparation of a Commission Directive establishing a fourth list of indicative occupational exposure limit values (IOELVs) under Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (2014), and its [supplementary opinion](#) on the preparation of a Commission Directive establishing a fourth list of indicative occupational exposure limit values (IOELVs) under Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

diseases. It pointed to 'the need to improve the evidence base for statistics on work-related accidents and diseases, including occupational exposures'. In this regard it called for a 'better analysis of cost-benefits on health and safety at work'. The European Federation of Building and Woodworkers (EFBWW) [called upon](#) the Commission to prepare a strategy to eradicate asbestos in Europe.

8. Conclusions

Despite wide-ranging European legislation, not all substances that can increase the risk of occupational cancers are necessarily covered by existing pieces of legislation. Various studies point to a continuous increase in cancers attributable to working conditions and to a need to improve the protection of workers. Although Directive 2007/34 is the main legislative act setting the standards for the protection of workers against work-related cancers, several studies and stakeholders have called for the scope of the directive to be broadened by adding chemical substances that were not originally covered by the directive, thus decreasing workers' exposure to them. Similarly, Parliament has on numerous occasions asked the Commission to amend the existing legislation on the prevention of work-related cancers and to increase workers' protection against occupational diseases, including cancer.

Although the May 2016 Commission proposal intends to increase the protection of workers by broadening of the scope of Directive 2007/34 by setting exposure limit values for 13 additional chemical substances, there are still various substances that are not included on the list and that can potentially have an adverse impact on the health of workers. The European Commission has promised to conduct a further impact assessment for the additional 12 chemical substances by the end of 2016. These subsequent actions may lead to future legislative proposals updating the existing legislation.

9. Other sources of reference

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