

ASSEMBLY OF THE REPUBLIC
EUROPEAN AFFAIRS COMMITTEE

Opinion
COM (2016) 248

PART I – INTRODUCTORY NOTE

Pursuant to Article 7 of Law 43/2006 of 25 August 2006 on the monitoring, examination and issuing of opinions by the Assembly of the Portuguese Republic in the context of the process of EU integration, as amended by Law 21/2012 of 17 May 2012, and in accordance with the Guidelines for the Scrutiny of EU Initiatives approved on 8 January 2013, the European Affairs Committee received a Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work [COM (2016) 248].

In view of its subject matter, the initiative in question was sent to the Social Security and Employment Committee, which has examined it and unanimously approved the report attached to this Opinion, which forms an integral part thereof.

The above-mentioned initiative was also sent to the Legislative Assembly of the Autonomous Region of Madeira, which scrutinised it when assessing the European Commission's Work Programme for 2016 and delivered a unanimous favourable opinion, which is also attached.

PART II – RECITALS

1. This initiative relates to the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work [COM(2016)248].

2. The proposal aims to improve workers' health protection by reducing occupational exposure to carcinogenic chemical agents, to increase the effectiveness of the European Union legislation in this area and to provide more clarity and a more level playing field for economic operators.

In this context, it should be recalled that it is among the priority actions identified in the Commission Work Programme for 2016.

The proposal also states that the Commission is delivering on its commitment to improve the efficiency and effectiveness of the protection of workers.

3. In this context, it states that estimates of the recent and future burden of occupational diseases indicate that work-related cancer is a problem and will remain so in the future as a result of exposure of workers to carcinogens.

Cancer is the primary cause of work-related deaths in the European Union. Every year, 53 % of work-related deaths are due to cancer, compared to 28 % for circulatory diseases and 6 % for respiratory diseases¹.

¹ European estimates of work-related injury and ill health, Work-related Illnesses Identification, Causal Factors and Prevention Safe Work — Healthy Work — For Life, Takala, J., Workplace Safety and Health Institute, Singapore, presentation to EU Presidency Conference, Athens, June 2014.

4. The Commission thus proposes to revise or to introduce exposure limit values for 13 chemical agents. According to the impact assessment conducted, it is estimated this will save around 100 000 lives by 2069.

The limit values are proposed to be introduced in Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work².

5. That Directive sets a number of general minimum requirements to eliminate or reduce exposure to all carcinogens and mutagens falling under its scope.

'Employers must identify and assess risks to workers associated with exposure to specific carcinogens (and mutagens), and must prevent exposure where risks occur.

Substitution of a non or less-hazardous process or chemical agent is required where this is technically possible. Where substitution is not technically possible chemical carcinogens must, as far as is technically possible, be manufactured and used in a closed system to prevent exposure. Where this is not technically possible, worker exposure must be reduced to as low a level as is technically possible. This is the minimisation obligation under Article 5(2) and Article 5(3) of the Directive'.

6. Regarding consistency with other Union policies, the initiative states that improving working conditions and preventing workers from suffering serious accidents or occupational diseases and promoting workers' health throughout their working life, is a key principle in line with the ambition to build a more social Europe, as defined by President Juncker in his political guidelines.

It also has a positive impact on productivity and competitiveness and is essential to promote longer working lives in line with the Europe 2020 strategy's objectives for smart, sustainable and inclusive growth³.

7. This initiative thus fits within the Commission's priority for a deeper and fairer single market, in particular its social dimension. It is in line with the Commission's work to establish a fair and truly pan-European labour market that provides workers with decent protection and sustainable jobs⁴. This includes occupational health and safety protection, social protection, and rights connected to the employment contract.

8. It should also be said that this initiative respects the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular in Article 31(1) thereof⁵.

9. The proposal does not require additional budget and staff resources for the EU budget or bodies set up by the EU.

² Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Text with EEA relevance) (OJ L 158, 30.4.2004, p. 50).

³ COM(2010) 2020 and COM(2014) 130 final.

⁴ President Juncker's State of the Union address in the European Parliament on 9 September 2015.

⁵ 'Fair and just working conditions'.

10. Lastly, it should be noted that the Report submitted by the Committee on Social Security and Labour, which was approved unanimously, fully reflects the content of the Proposal. It should therefore be reproduced in full. This therefore serves to avoid repetition of analysis and consequent redundancy.

In the light of the provisions made in the Proposal, the following must be considered:

a) Legal basis

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

It is emphasised that Article 153(1)(a) TFEU states that the Union shall support and complement the activities of the Member States in the field of ‘improvement in particular of the working environment to protect workers’ health and safety’.

b) Principle of subsidiarity

It is important to note that minimum standards for workers’ health protection against the risks arising from exposure to these carcinogens cannot be ensured for all EU workers in all Member States by actions taken by Member States alone.

Accordingly, and bearing in mind that the objectives of this initiative, which are to improve living and working conditions and to protect the health of workers from the specific risks arising from exposure to carcinogens, cannot be sufficiently achieved by the Member States, but can be better achieved at EU level, the EU may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on European Union.

The principle of subsidiarity is therefore duly enforced and respected.

In accordance with the principle of proportionality, as set out in Article 5(4) of the TEU, this initiative does not go beyond what is necessary in order to achieve those objectives.

Moreover this initiative will encourage more flexibility in cross-border employment, because workers can be reassured that they will enjoy minimum standards and levels of protection of their health in all the Member States.

PART III – OPINION

In the light of the information set out above and the report of the relevant committee, the European Affairs Committee's opinion is as follows:

1. This initiative is not in breach of the principle of subsidiarity, in so far as the objective pursued will be achieved more effectively by means of action at Union level.
2. This concludes the scrutiny of this initiative.

Palácio de S. Bento, 12 July 2016

Rapporteur
(António Ventura)

President of the Committee
(Regina Bastos)

PART IV – ANNEX

- Report from the Social Security and Employment Committee
- Report and Opinion of the Legislative Assembly of the Autonomous Region of Madeira.

Assembly of the Republic

Labour and Social Security Committee

**REPORT OF THE LABOUR AND SOCIAL SECURITY
COMMITTEE**

Proposal for a DIRECTIVE OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL amending Directive
2004/37/EC on the protection of workers from the risks related to
exposure to carcinogens or mutagens at work

Rapporteur: Sandra
Pereira

CONTENTS:

I – INTRODUCTORY NOTE

II – RECITALS

1. Objective of the Proposal
2. Background to the Proposal
3. The proposed changes
4. Legal basis
5. Democratic principles applicable in the light of the Lisbon Treaty

III – CONCLUSIONS

IV – OPINION:

I – INTRODUCTORY NOTE

Pursuant to Article 163 of the Constitution of the Portuguese Republic and Law No 43/2006 of 25 August 2012, amended by Law No 21/2012 of 17 May 2012, [monitoring, examination and pronouncement by the Assembly of the Republic on matters relating to the construction of the European Union], the Assembly of the Republic is responsible for following up European initiatives and may, in particular, scrutinise proposals for legislative acts and issue reports and opinions.

The European Affairs Committee received the Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

In this context, pursuant to the Law on monitoring, examination and pronouncement by the Assembly of the Republic on matters relating to the construction of the European Union and the guidelines for scrutiny of European initiatives, the European Affairs Committee asked the Labour and Social Security Committee to assess the initiative's compliance with the principle of subsidiarity and proportionality pursuant to Protocol No 2 annexed to the Treaty of Lisbon.

Accordingly, the Labour and Social Security Committee duly considered the initiative and issued this report on the above-mentioned Proposal for a Directive of the European Parliament and of the Council.

II – RECITALS

1. Objective of the Proposal

The proposal pursues the following objectives:

- to improve workers' health protection by reducing occupational exposure to carcinogenic chemical agents;
- to increase the effectiveness of the EU legislation in this area and harmonise it;
- to provide more clarity and a more level playing field for economic operators.

2. Background to the Proposal

It is among the priority actions identified in the Commission Work Programme for 2016 under 'a new boost to jobs, growth and investment'. The Commission expressly states that 'our review of the existing occupational health and safety legislation, including on carcinogens and mutagens, will improve the efficiency and effectiveness of an EU framework for protecting workers.'

Estimates of the recent and future burden of occupational diseases indicate that work-related cancer is a problem and will remain so in the future as a result of exposure of workers to carcinogens. Cancer is the primary cause of work-related deaths in the EU. Every year, 53% of work-related deaths are due to cancer, compared to 28% for circulatory diseases and 6% for respiratory diseases.

Occupational cancer impacts the economy at large, reducing labour supply (either temporarily or permanently), decreasing labour productivity and increasing the burden on public finances

through avoidable public expenditure on health care, disability benefits, pensions for early retirement, and other benefits. For the workers and their families, cancer results not only in substantial quality of life losses, but also in direct health care costs and indirect loss of present and future earnings. For business, occupational cancer implies staff replacement costs, productivity losses and the need to pay higher wages to compensate for the higher occupational risk, which affects their competitiveness.

Exposure to specific chemical agents at work increases the risks of contracting the disease, for which reason, to protect workers against those risks, the EU adopted Directive 2004/37/EC, the Carcinogens and Mutagens Directive, which defines the measures to be taken to eliminate or limit exposure to carcinogenic chemicals and lays down exposure limit values for the workplace. However, the Directive became obsolete, given that it does not take account of the scientific data now available, and should be updated.

But the current differences between the limit values set in the Member States for occupational exposure to the carcinogens identified mean that no minimum standards are in place for equal protection of all workers in the EU. The current situation also creates an unlevel playing field for firms as those operating in Member States with less protective OELs have a competitive advantage. Action taken by Member States alone cannot address these concerns, and there are therefore grounds for EU-level action to achieve this objective, in line with Article 5(3) TEU.

The Commission proposes to revise or to introduce exposure limit values for 13 chemical agents. According to the impact assessment, it is estimated this will save around 100 000 lives by 2069.

The limit values to be introduced in Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work are proposed in Article 16 of the Directive, which is reproduced in its entirety:

Article 16

Limit values

1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.

2. Limit values and other directly related provisions are set out in Annex III.

The provisions of the Directive also apply to any substance, mixture or process referred to in Annex I to that Directive, as well as to any substance or mixture released by a process referred to in that Annex. Annex I to the Directive currently includes a list of identified processes and process-generated substances. The aim is to clarify for workers, employers, and the authorities whether a given chemical agent or process, if it has not otherwise been classified according to Regulation (EC) No 1272/2008, is in the scope of the Directive. Currently, Annex I has five entries.

The Directive sets a number of general minimum requirements to eliminate or reduce exposure for all carcinogens and mutagens falling under its scope. Employers must identify

and assess risks to workers associated with exposure to specific carcinogens (and mutagens), and must prevent exposure where risks occur.

In addition to these general minimum requirements, the Directive clearly indicates that the setting of occupational exposure limit values for the inhalation route of exposure for particular carcinogens and mutagens is an integral part of the mechanism for protecting workers. Those values still need to be set for the chemical agents for which no such values exist and be revised whenever this becomes possible in the light of more recent scientific data. Concrete exposure limit values for specific chemical agents are set in Annex III to the Directive. Currently, Annex III has three entries.

From the spirit of the Directive it follows that the occupational exposure limit values set in it should when appropriate be revised to take into account new scientific data, improvements in measurement techniques, risk management measures and other relevant factors.

3. The proposed changes:

The proposed amendment of Directive 2004/37/EC will involve three specific measures:

a) Include in Annex I to the Directive work involving exposure to respirable crystalline silica dust generated by a work process and establish a corresponding limit value in Annex III.

Crystalline silica placed on the market is subject to the classification obligation under Regulation (EC) No 1272/2008, while crystalline silica dust generated by a work process is not placed on the market and therefore is not classified in accordance with that Regulation. However, the Directive makes provisions for the inclusion in Annex I of substances or mixtures released by a process referred to in that Annex which, although not subject to the classification obligation in accordance with the said Regulation, meet the criteria for classification as a carcinogen. Respirable crystalline silica dust falls within this category.

The limit value to be introduced in Annex III proposed in this initiative and agreed by the Advisory Committee on Safety and Health at work (ACSH) reflects socio-economic feasibility factors, while maintaining the aim of ensuring the protection of workers' health.

b) Establish in Annex III limit values for 10 additional carcinogens.

Available scientific evidence confirms the need to complete Annex III with limit values for 10 additional carcinogens. SCOEL (the Scientific Committee on Occupational Exposure Limits) submitted recommendations for all but two of these agents (o-toluidine and 2-nitropropane). For these, the Commission principally referred to scientific information available in the public domain, including to conclusions of national scientific committees that set occupational exposure limit values. The Advisory Committee on Safety and Health at work (ACSH) was consulted on all aspects of this proposal, in accordance with Article 2(2)(f) of the Council Decision of 22 July 2003. With regard to the values proposed, socio-economic feasibility factors have been taken into account further to the consultation of the ACSH.

c) Revise the existing limit values for hardwood dusts and vinyl chloride monomer in the light of available scientific data.

For two of the three existing limit values established in Annex III to the Directive, namely on work involving exposure to hardwood dust and vinyl chloride monomer, SCOEL adopted

revised recommendations, in 2003 and 2004 respectively. These recommendations indicated a need to consider revising existing limit values for hardwood dusts and vinyl chloride monomer, which were estimated to be too high to properly protect workers. It is therefore appropriate to revise the current limit values for hardwood dusts and vinyl chloride monomer in the light of more recent scientific data.

4. Legal basis

Article 153(2)(b) TFEU provides that the European Parliament and the Council ‘may adopt, in the fields referred to in paragraph 1(a) to (i) [of Article 153 TFEU], by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. Such directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings’. Article 153(1)(a) TFEU states that the Union shall support and complement the activities of the Member States in the field of ‘improvement in particular of the working environment to protect workers’ health and safety’.

Directive 2004/37/EC was adopted on the basis of Article 153(2)(b) with the aim to improve workers’ health and safety. On that basis, Article 16 of Directive 2004/37/EC provides for the adoption of limit values in accordance with the procedure laid down in Article 153(2) TFEU in respect of all those carcinogens or mutagens for which this is possible.

As stated, the objective of the present proposal is to strengthen the level of worker health protection in line with Article 153(1)(a) TFEU, by including in Annex I to Directive 2004/37/EC work involving exposure to respirable crystalline silica dust (respirable fraction) generated by a work process. This is also achieved through the establishment of additional minimum requirements for workers’ health protection in the form of limit values in Annex III to the Directive, and the revision of the current limit values in Annex III for two carcinogens in the light of more recent scientific data. **Consequently, Article 153(2)(b) TFEU constitutes the proper legal basis for the Commission’s proposal.**

Thus, pursuant to Article 153(2) TFEU, the improvement in particular of the working environment to protect workers’ health and safety is an aspect of social policy where the EU shares competence with the Member States.

5. Democratic principles applicable in the light of the Lisbon Treaty

• The principle of subsidiarity

The principle of subsidiarity applies, given that the proposal is not an exclusive competence of the EU but calls for shared management arrangements. The objectives of the proposal cannot be sufficiently achieved by the Member States and can, therefore, in view of their dimension and their effects, be better achieved at EU level.

By way of illustration, as risks to workers’ health and safety are broadly similar across the EU, there is a clear role for the EU in supporting Member States to address such risks. There is evidence of wide differences in the Member States regarding the setting of limit values for the carcinogens under this proposal. Some Member States have already established binding limit values that are at the same value or lower than the value recommended by the ACSH. This demonstrates that unilateral national action is possible as regards setting a limit value for

these chemical agents. However, there are also many cases where Member States have no limit values or ones that are less protective of worker health than the value put forward in this proposal. In addition, where national limit values exist, they vary considerably, leading to different levels of protection, generating disparities on a market which aims to be as uniform as possible where workers' safeguards are concerned. Furthermore, some of these limits are considerably higher than recommended by scientific evidence.

Under such circumstances minimum standards for workers' health protection against the risks arising from exposure to these carcinogens cannot be ensured for all EU workers in all Member States by actions taken by Member States alone. It follows that action taken at EU level to achieve the objectives of this proposal appears to be necessary and in line with Article 5(3) of the TEU, which provides that 'The Union may take initiatives to ensure coordination of the Member States' social policies'. Moreover, this proposal will encourage more flexibility in cross-border employment, because workers can be reassured that they will enjoy minimum standards and levels of protection of their health in all the Member States.

• **The principle of proportionality**

In terms of the principle of proportionality, this proposal does not go beyond what is necessary in order to improve EU workers' living and working conditions. The values proposed by the amendment to the Directive were duly weighted against socio-economic feasibility factors after long and intensive discussions with all stakeholders (representatives from employees' associations, representatives from employers' associations, and representatives from governments).

This proposal leaves Member States the possibility to keep or set more favourable standards for workers and the flexibility to take into account features specific to their national situation.

In accordance with Article 153(4) TFEU, the provisions in this proposal do not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties, in the form for example of lower limit values. Article 153(3) TFEU gives Member States the possibility to entrust management and labour, at their joint request, with the implementation of directives adopted pursuant to Article 153(2) TFEU, thus respecting well established national arrangements for regulation in this area.

It follows that in line with the principle of proportionality, as set out in Article 5(4) of the TEU, this proposal does not go beyond what is necessary in order to achieve those objectives.

PART III – CONCLUSIONS

In view of the above, the Labour and Social Security Committee concludes as follows:

1. The European Affairs Committee referred this proposal to the Labour and Social Security Committee for an opinion;
2. The purpose of the proposal under assessment is to amend Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work;
3. The objectives of this proposal cannot be sufficiently achieved unilaterally by the Member States, but can be better achieved more efficiently at EU level, and there is therefore no breach of the principle of subsidiarity;

4. Likewise, as it upholds the principle of proportionality, the proposal does not go beyond what is necessary in order to achieve the objectives set, and the principle of proportionality enshrined in Article 5(3) of the Treaty on European Union is also upheld;
5. The Labour and Social Security Committee considers its examination of this initiative to be complete.

IV – OPINION:

The Labour and Social Security Committee is of the following Opinion:

- a) Pursuant to Law No 43/2006 of 25 August 2006, as amended by Law No 21/2012 of 17 May 2012, this report should be submitted to the European Affairs Committee for the applicable legal and regulatory purposes.
- b) The scrutiny of this initiative is hereby concluded.

Palácio de S. Bento, 15 June 2016.

Rapporteur
(Sandra Pereira)

President of the Committee
(Feliciano Barreiras Duarte)

AUTONOMOUS REGION OF MADEIRA
LEGISLATIVE ASSEMBLY
1st Specialised Standing Committee on General Policy and Youth

Report and Opinion

European Commission Work Programme for 2016, on the Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

CHAPTER I
Introduction

At the request of the President of the Legislative Assembly, the Specialised Standing Committee on General Policy and Youth met on 3 June 2016 to assess and give an opinion on the above-mentioned proposal.

The request for an opinion was received in the Legislative Assembly of the Autonomous Region of Madeira on 24 May 2016 and was referred to the Specialised Standing Committee on General Policy and Youth, which was asked to provide its opinion by 14 June 2016.

CHAPTER II:
Legal framework and background

The initiative is assessed pursuant to Article 229(2) of the Constitution of the Portuguese Republic, Article 36(1)(i) and Articles 89 and 90 of the Political and Administrative Statute of the Autonomous Region of Madeira, approved by Law No 130/99 of 21 August 1999, and also in line with Article 44(j) of the Rules of Procedure of the Legislative Assembly of the Autonomous Region of Madeira.

In view of the subject matter, pursuant to Article 43 of the Rules of Procedure, it falls to the Specialised Standing Committee on General Policy and Youth to give an opinion on behalf of the Legislative Assembly.

CHAPTER III:
Assessment of the initiative

An opinion was requested on the Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

The proposal aims to '... improve workers' health protection 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 more level playing field for economic operators. It is among the priority actions identified in the Commission Work Programme for 2016. With this initiative the Commission delivers on its commitment to improve the efficiency and effectiveness of an EU framework for protecting workers. The intention is also to continue this important work and to conduct further impact assessments with a view to propose limit values for additional carcinogens.

Thus, in view of the above, the Committee decided that it did not have any objections to the proposal under consideration.

CHAPTER IV
Conclusions and opinion

On the basis of its assessment, the Specialised Standing Committee on General Policy and Youth decided unanimously to give a favourable opinion on the proposal referred to it.

Funchal, 3 June 2016.

Rapporteur
(Carolina Silva)

President
(Adolfo Brazão)