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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	22 September 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2020) 571 final
Subject:	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.

Delegations will find attached document COM(2020) 571 final.

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2020/0262 (COD)

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.

{SEC(2020) 302 final} - {SWD(2020) 183 final} - {SWD(2020) 184 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Reasons for and objectives of the proposal

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

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

Cancer is also the first cause of work-related deaths in the EU[3]: 52% of annual occupational deaths are currently attributed to work-related cancers, compared to 24% to circulatory diseases, 22% to other diseases and 2% for injuries. Addressing occupational cancer through this and other initiatives will also be an integral part of Europe's Beating Cancer Plan. This proposal specifically aims to improve workers' health and safety protection by reducing occupational exposure to three carcinogenic substances or groups of substances (hereafter "substances"), to provide more clarity for workers, employers and enforcers, and to contribute to a level playing field for economic operators.

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

In order to build a strong social Europe after the crisis, and as the EU economy recovers, constant improvements towards safer and healthier work for all are needed. Moreover, as outlined in the Communication on "A strong social Europe for just transitions"[4], measures for the protection of workers need to keep up with a wide range of social, economic and technological developments while ensuring continuous protection from traditional risks.

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

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

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

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

In its Communication, the Commission has already committed to review the occupational health and safety (OSH) strategy to address among others the exposure to dangerous substances, with a view to maintain European's high OSH standards. The European Pillar of Social Rights[5], jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, enshrines workers' right to healthy, safe and well-adapted work environment, including protection from carcinogens. In its Communication on "Safer and Healthier Work for All,"[6] the Commission also emphasizes that European Union must continue investing in occupational safety and health and has committed to step up the fight against occupational cancer through legislative proposals. The recent extension of the Roadmap on Carcinogens[7] covenant, which was signed in Helsinki on 28 November 2019, also proves that a significant number of stakeholders continue to be committed to improve the protection of workers from the exposure to carcinogenic substances.

In order to further contribute to a better protection of workers, the Commission pursues its process of updating the Carcinogens and Mutagens Directive (hereafter 'the Directive')[8] to keep abreast with the new scientific and technical developments and take into account of its stakeholders' views. Pursuant to Article 16 of the Directive, Occupational Exposure Limit values (OELs) shall be set, 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, in Annex III to the Directive. As provided by Article 17(1), Annex III to the Directive may be amended in accordance with the procedure laid down in Article 153(2) of the Treaty on the Functioning of the European Union (TFEU), i.e. the ordinary legislative procedure.

Over the last few years, the Commission proposed three directives amending the Directive. These three directives have been adopted by the European Parliament and the Council in December 2017[9], January 2019[10] and June 2019[11]. These three revisions, which addressed 26

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

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

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

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

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

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

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

substances in total, enabled among others to revise two existing OELs, introduce 22 new OELs and set a skin notation[12] for the remaining two (without setting OELs).

With a view to propose this fourth amendment of the Directive, the Commission carried out a two-stage consultation of the social partners at the European level in July[13] and November 2017[14], in accordance with Article 154 of the TFEU. Both workers' and employers' organisations confirmed that the three substances below are of high relevance for the protection of workers and encouraged the Commission to continue the preparatory work for the establishment of OELs for those priority carcinogens:

- Acrylonitrile
- Nickel compounds
- Benzene

This list was reconfirmed by Member States' authorities, employers' and workers' organisations within the framework of the tri-partite Advisory Committee on Safety and Health at Work (ACSH) via its dedicated Working Party on Chemicals (WPC) in accordance with its mandate in which the Commission requests the active engagement of the WPC in recommending priorities for new or revised scientific evaluations.

More than one million of workers are currently exposed to acrylonitrile, nickel compounds or benzene. If no action is taken at the EU level, these workers will continue to run the risk of contracting a cancer or suffer from other severe health problems. Detailed information about the different uses of these three substances and how they affect workers, as well as the specific sectors in which workers are exposed to them are provided in the impact assessment accompanying this proposal.

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 at the workplace, and must prevent exposure where risks occur. Substitution with 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 it 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.

In addition to these general minimum requirements, the Directive clearly indicates that the setting of OELs for the inhalation route of exposure for carcinogens and mutagens for which

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12 A skin notation identifies the possibility of significant uptake through the skin.

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

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

this is possible is an integral part of the mechanism for protecting workers[15]. 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[16]. OELs for specific carcinogens or mutagens are set in Annex III to the Directive.

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

Available information, including scientific data, confirms the need to complete Annex III with new or revised OELs for the three before mentioned carcinogenic substances. It also confirms the need to maintain or add skin notations for acrylonitrile and benzene as well as a notation for dermal[17] and respiratory[18] sensitisation for nickel compounds.

On this basis, it is proposed to take specific measures with a view to establish OELs in Annex III for acrylonitrile and nickel compounds, and revise the OEL for benzene. In addition to these OELs, it is also proposed to add in Annex III skin notation for acrylonitrile as well as a notation for dermal and respiratory sensitisation for nickel compounds. The existing skin notation for benzene has also been kept.

Consistency with existing policy provisions in the policy area

This initiative is in line with the European Pillar of Social Rights proclaimed in 2017[19], in particular its 10th principle enshrining the workers' right to healthy, safe and well-adapted work environment. Setting new or revised OELs contributes to a high level of protection of workers' health and safety.

This initiative is also in line with the Communication on "Safer and Healthier Work for All"[20] in which the Commission emphasizes that European Union must continue investing in occupational safety and health and has committed to step up the fight against occupational cancer through legislative proposals.

Consistency with other Union policies

Europe's Beating Cancer Plan

15 Article 1 (1) and recital 13 of the Directive

16 Article 16 (1) and recital 13 of the Directive

17 A notation for "dermal sensitisation" means that exposure to a substance can cause adverse skin reactions.

18 A notation for "respiratory sensitisation" means that exposure to a substance by inhalation can cause adverse reactions in the respiratory tract.

19 See footnote 5

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

In her political guidelines for the European Commission[21], President von der Leyen recognized that there is much more the European Union can do about cancer and committed to put forward a European plan to fight cancer. On 4 February 2020, the Commission launched an EU-wide public consultation on Europe's Beating Cancer Plan on the occasion of a conference entitled "Europe's Beating Cancer Plan: Let's Strive for More" hosted in the European Parliament.

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

Charter of Fundamental Rights of the EU

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

REACH Regulation

The REACH Regulation[22], which entered into force in 2007, consolidated and evolved several parts of the EU chemicals legislation, including those relating to risk assessment and to the adoption of the risk management measures. This Regulation establishes among others two distinct EU regulatory approaches that are restrictions and authorisations. Restrictions enable the EU to impose conditions on the manufacturing, placing on the market and/or use of a substances on its own, in a mixture or in an article, and authorisation is designed to ensure that the risk of substances of very high concern (SVHCs) is properly controlled while promoting progressive substitution by suitable alternatives that are economically and technically viable[23].

The applicable provisions of REACH authorisation and/or restriction of the chemical substances under consideration in this proposal are as follows:

- Restriction: placing on the market and use of benzene and its mixtures with few exemptions, placing on the market and use of nickel and its compounds in jewellery and articles which are intended to come into contact with the skin, placing on the market or used for supply to the general public of acrylonitrile and its mixtures.
- Authorisation: none of these substances are subject to authorisation under REACH.

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21 See footnote 2

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

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

The Directive and REACH Regulation are legally complementary. The OSH Framework Directive 89/391/EEC[24], lays down the main principles of the prevention and protection of occupational risks and applies to all sectors of activities. It foresees its application without prejudice to existing or future national and EU provisions which are more favourable to protection of the health and safety of workers at work. A series of individual Directives in the area of OSH were adopted on the basis of Article 16 of the OSH Framework (including the Directive). REACH Regulation in turn states that it applies without prejudice to worker protection legislation, including the Directive.

In the context of the complementary operation of the Directive and REACH Regulation it makes sense to propose limit values under the Directive for the following reasons:

- The Directive covers any use of a carcinogen or mutagen at the workplace through its entire lifecycle, and covers worker exposure to those agents released by any work activity, whether produced intentionally or not, and whether available on the market or not.
- The risk assessment performed by the employers under Directive 2004/37/EC is workplace-related and process-specific and should also take into account aggregated exposure of workers during their daily working activity to all carcinogens and mutagens present at the workplace.
- OELs for carcinogens and mutagens are set via a robust process – ultimately passing through the co-legislator for adoption – based on available information, including scientific and technical data and stakeholders' consultation.
- OELs are an important part of the Directive and of the wider OSH approach to managing chemical risks.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

Legal basis

Article 153(2)(b) of the TFEU provides that the European Parliament and the Council 'may adopt, in the fields referred to in paragraph 1(a) to (i) [of Article of the 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) of the 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) of the TFEU with the aim to improve workers' health and safety. Article 16 provides for the adoption of limit values in accordance with the procedure laid down in Article 153(2) of the TFEU in respect of all those carcinogens or mutagens for which this is possible.

The objective of the present proposal is to strengthen the level of worker health protection in line with Article 153(1)(a) of the TFEU, in the form of new or revised limit values as well as

[24] OJ L 183, 29.6.1989, p.1.

notations in Annex III to the Directive. Article 153(2)(b) of the TFEU therefore constitutes the proper legal basis for the Commission's proposal.

Pursuant to Article 153(2) of the 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.

Subsidiarity (for non-exclusive competence)

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.

Data gathered in the preparatory work indicate wide differences in the Member States regarding the setting of limit values for the carcinogens under this proposal[25]. 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 effective 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 limit values that are less protective of worker health than the value put forward in this proposal. In some other cases, Member States have no limit values for these carcinogens. In addition, where national limit values exist, they vary considerably, leading to different levels of protection.

Under such circumstances, minimum requirements 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.

Diverging levels of protection may also provide incentives for companies to locate their production facilities in Member States with the lower requirements. In all cases, differences in labour requirements have an impact on competitiveness, because they impose different costs on operators. This effect on the single market may be reduced through the establishment at EU level of clear specific minimum requirements for worker protection in the Member States.

It follows that action taken at EU level to achieve the objectives of this proposal is necessary and in line with Article 5(3) of the TEU. Amending the Directive can only be done at EU level and after a two-stage consultation of the social partners (management and labour) in accordance with Article 154 of the TFEU.

Proportionality

This proposal makes a step forward to achieve the objectives set to improve living and working conditions of workers.

With regard to the limit values proposed, socio-economic feasibility factors have been taken into account after intensive discussions with all stakeholders (representatives of workers' organisations, representatives of employers' organisations, and representatives of governments).

In accordance with Article 153(4) of the 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) of

[25] See table 3 in the impact assessment.

the 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) of the 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.

Choice of the instrument

Article 153(2)(b) of the TFEU specifies that minimum requirements in the field of workers' health and safety protection may be adopted 'by means of directives'.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

Ex-post evaluations/fitness checks of existing legislation

The ex-post evaluation of the European Union occupational safety and health Directives[26] (REFIT evaluation) emphasizes that chemicals classified as carcinogens and mutagens continue to be manufactured across the EU. Workers in manufacturing and downstream users are also exposed to them. The main conclusions of this evaluation indicates that the Directive is considered as of high relevance. Following concerns raised by different stakeholders' groups in the evaluation process and in the National Implementation Reports, the need to adopt limit values for more substances should be considered. Amending the Directive by setting or revising OELs for three substances should lead to a better chemical risk management in the future and improve workers' health and safety protection.

Stakeholder consultations

Two stage consultation of the European social partners in accordance with Article 154 of the TFEU

In 2017[27], the Commission carried out a two-stage consultation of the social partners at the EU level pursuant to Article 154 (2) of the TFEU. The first phase of social partners' consultation closed on 30 September 2017 and three substances have been identified for this initiative. The second phase consultation closed on 22 December 2017 and confirmed these three substances as to be addressed in this initiative.

This consultation also enabled to collect social partners' opinions on the possible direction and content of EU action regarding the establishment and/or revision of binding OELs in Annex III to the Directive, as well as regarding future revisions of the Directive.

The results of the first phase consultation confirmed that action needs to be taken at EU level to introduce better standards across the EU, and to tackle situations involving workers' exposure.

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

27 This two-stage consultation covers the third and fourth (current initiative) revisions of the CMD in order to save time and deliver them more quickly. This explains why the timing gap between the consultation and this initiative is longer than usual.

The three workers' organisations[28] that replied to the consultation, all acknowledged the importance of the existing legislation and a need for further action. They agreed, broadly, with the issues described in the consultation document and confirmed the importance they attach to protecting workers from the health risks associated with exposure to carcinogens and mutagens, stressing the need of continuous inclusion of new or revised OELs in Annex III.

The four employers' organisations[29] that replied to the consultation supported the objective to effectively protect workers from occupational cancer, including by setting binding OELs at EU level. Concerning the issues identified in the consultation paper, the employers in principle supported further revisions of the Directive, subject to certain conditions. In their opinion, binding OELs should be set for priority substances only. The process of OELs setting should be based on sound scientific evidence, technical and economic feasibility, socioeconomic impact assessment and opinion of the tripartite ACSH.

The second phase of the social partners' consultation closed on 22 December 2017. The consultation document for this second phase considered the possible avenues for EU action to improve workers' protection against carcinogens or mutagens.

The three workers' organisations[30] that replied to the second phase consultation recognised the importance of further improving the existing legislative framework in line with the proposed Commission action and beyond with a view to continuously tackle the risks caused by the exposure to carcinogens and mutagens. They reiterated the need to reach the objective of setting 50 OELs for carcinogens and mutagens by 2020.

The four employers' organisations[31] that replied to the second phase consultation, they confirmed their support to actions aiming to effectively protect workers from occupational cancer, including the setting of binding OELs at EU level but underlined the need to ensure values that are proportionate and feasible to be implemented in technical terms. While employers considered that the Commission's criteria for prioritising substances are relevant, they suggested in particular that the criteria of technical and economic feasibility should also be included.

It resulted from those social partners' consultations, that it would be appropriate to add new or revised OELs for the three carcinogens through a fourth amendment of the Directive.

Consultation of the Advisory Committee on Safety and Health at Work

The ACSH, composed of three full members per Member State, representing national governments, workers' and employers' organisations, is consulted on regular basis. It gives, taking into account the input of the Risk Assessment Committee (RAC) of the European

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28 European Trade Union Confederation (ETUC), European Confederation of Independent Trade Unions (CESI) and European Federation of Building and Woodworkers (EFBWW)

29 BusinessEurope, European Association of Craft Small and Medium-sized Enterprises (UEAPME), European Chemical Employers Group (ECEG) and Council of European Employers of the Metal, Engineering and Technology-based industries (CEEMET)

30 European Public Service Union (EPSU), European Trade Union Confederation (ETUC) and European Federation of Building and Woodworkers (EFBWW)

31 BusinessEurope, European Association of Craft Small and Medium-sized Enterprises (UEAPME), European Chemical Employers Group (ECEG) and Council of European Employers of the Metal, Engineering and Technology-based industries (CEEMET)

Chemicals Agency (ECHA) as well as socio-economic and feasibility factors, opinions which are used to prepare the Commission's proposal.

The ACSH has adopted opinions for acrylonitrile[32], nickel compounds[33] and benzene[34] in the framework of this fourth revision of the Directive. The ACSH is proposing as possible approaches for these chemicals one or several binding OELs with additional notations for all of them. Although Biological Limit Values (BLVs) are not proposed under the CMD, the ACSH agreed on the usefulness of biomonitoring for benzene and on the BLV for acrylonitrile as proposed by RAC.

Collection and use of expertise

In reviewing or setting new limit values under the Directive, the Commission follows a specific procedure, which involves seeking scientific advice and consulting the ACSH. Sound scientific basis is indispensable to underpin any occupational safety and health action, particularly in relation to carcinogens and mutagens. In this regard, with a view to mainstream scientific advice and in line with the Commission Communication on "Safer and Healthier Work for All"[35] of 10 January 2017, the Commission seeks advice from ECHA's RAC.

RAC develops high quality comparative analytical knowledge and ensures that Commission proposals, decisions and policy relating to the protection of workers' health and safety are based on sound scientific evidence. Members of RAC are highly qualified, specialized, independent experts selected on the basis of objective criteria. They provide the Commission with opinions that are helpful for the development of EU policy on workers protection.

For this initiative, RAC provided three scientific opinions for OELs on acrylonitrile[36], nickel compounds[37] and benzene[38] in which it evaluates the health effects of chemical agents on workers based on sound scientific evidence. RAC assisted the Commission, in particular, in evaluating the latest available scientific data and in proposing OELs for the protection of workers from chemical risks, to be set at EU level pursuant to the Directive. Although Biological Limit Values (BLVs) are not proposed under the CMD, RAC recommended BLVs for acrylonitrile and benzene.

Following the two-stage consultation of the European social partners, the Commission's Directorate-General for Employment, Social Affairs and Inclusion launched on 9 May 2018

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32 Available at: https://circabc.europa.eu/sd/a/df365d23-26f3-4266-8a55-4b60f631506e/Doc.1050-19-EN%20ACSH%20WPC_CMD__Opinion_acrylonitrile%20Adopted%2004062019.pdf

33 Available at: https://circabc.europa.eu/sd/a/4748ba6a-59aa-4349-9baa-f85dc59a4ed3/Doc.1054-19-EN_ACSH%20WPC_CMD_draft_Opinion_nickel%20rev-clean.pdf

34 Available at: https://circabc.europa.eu/sd/a/b28832c6-8cc6-4a6c-b966-986211b180fc/Doc.1056-19-EN-ACSH%20CMD_Opinion_benzene%20Adoped%2004062019.pdf

35 See footnote 6

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

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

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

an open call for tender[39]. The aim was to carry out an assessment of the social, economic and environmental impacts of a number of policy options concerning the protection of workers health from risks arising from possible exposure to a certain number of substances at the workplace, including acrylonitrile, nickel compounds and benzene. The contract started on 3 September 2018 and lasted 11 months. The outcome of this study provided the main basis for the impact assessment report accompanying this proposal.

Impact assessment

This proposal is supported by an impact assessment. The impact assessment report was reviewed by the Regulatory Scrutiny Board on 27 May 2020. It received a positive opinion with reservations. These were subsequently addressed in the final Impact Assessment Report.

The following options for different limit values and/or notations (skin notation, and respiratory and dermal sensitisation) for each of the three carcinogens were examined:

- A baseline scenario of no further EU action for each chemical agent in this initiative (option 1).
- In addition to the baseline scenario, options for OELs have been considered at the level proposed by the ACSH and at additional reference points (e.g. the strictest limit value observed among Member States, OELs derived by the RAC)

Several other options have been discarded at an early stage as they were considered disproportionate or less effective in reaching the objectives of this initiative. These discarded options are related either to the way of setting OELs, or to the choice of another instrument, or to the support of the SMEs. The discarded options related to the way of setting OELs were the ban of the use of the carcinogenic chemical agents and the adoption of the most stringent OEL among the EU Member States. The other instruments considered were industry-specific information without amending the Directive, market-based instruments, industry self-regulation, regulation under other EU instruments (REACH) and guidance documents. In addition to that, adopting solutions for SMEs was also discarded as a very significant number of European workers would have not been covered by this Directive.

An analysis of economic, social and environmental impacts of the different policy options for each chemical agent was carried out. The results of the study are presented in the Impact Assessment accompanying the present proposal. The comparison of the policy options and the choice of the preferred option were carried out on the basis of the following criteria: effectiveness, efficiency and coherence. Costs and benefits were calculated over a 60-year period, in line with the future cancer burden estimated over the same period, to take proper account of the cancer latency period. All analytical steps were performed in line with the Better Regulation Guidelines[40].

The measures resulting from the opinions of ACSH were retained and translated into legislative provisions in respect of all the chemical agents in this proposal, including transitional periods for the three substances. These transitional measures will enable

[39] Call for Tender documents available at: https://etendering.ted.europa.eu/cft/cft-display.html?cftId=3559

[40] Available at: https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en

companies to have more time to make the necessary investments while already improving the protection of workers. Indeed, although the annualised cost per company is expected to be sustainable, most investments in risk management measures (RMMs) would take place early in the 60-year period considered in the calculations. With regard to acrylonitrile and benzene, the OEL will apply after a 4-years transition period starting from the entry into force of this Directive. In addition, a transitional OEL for benzene will apply from two years up to four years after entry into force of this Directive. These transitional measures are considered as necessary and sufficient to enable companies to make the needed investments. For the specific case of nickel compounds, the transition measures will apply until 17 January 2025 in order to ensure alignment with the transitional measures adopted for chromium VI[41], which also apply until 17 January 2025. Indeed, both groups of substances (nickel compounds and chromium VI compounds) are frequently occurring in the same sectors and, often, in the same processes. As unanimously recommended by the ACSH[42], reducing the exposure to nickel compounds and chromium VI compounds must be coordinated and can benefit from synergies. Based on the analysis of the above suggestion as well as of the data resulting from the external study, the Commission considers appropriate that transition periods are established for the three substances

Impact on workers

As regards the impact on workers, this initiative should result in benefits in terms of avoided work-related cases of cancer and other serious illness, while reducing effects such as suffering of workers and their caring families, a reduced quality of life or undermined wellbeing.

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

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

Impact on employers

As regards the impact on employers, this initiative could result in higher costs for companies that will have to put in place additional protective and preventive measures. However, these investments will represent a small fraction of companies' turnover. Investments in protective measures will furthermore help companies to avoid costs related to personnel absence and decreased productivity, which could be otherwise caused by ill-health.

Furthermore, transitional measures are foreseen for the three substances so that companies would have more time to make the necessary investments while already improving the protection of workers. Indeed, although the annualised cost per company is expected to be

41 OJ L 345, 27.12.2017, p. 87

42 See footnote 33

sustainable, most investments in RMMs would take place early in the 60-year period considered in the calculations.

The proposal does not add information obligations and will thus not lead to an increase in administrative burdens on enterprises.

Impact on the environment

As regards the impact on the environment, the introduction of the OEL for acrylonitrile will not lead to further installation of local exhaust ventilations (LEVs) that might lead to increased emissions in the air. None of the potential RMMs to comply with the preferred option for acrylonitrile are expected to lead to significant changes in the releases of acrylonitrile to water. The introduction of the preferred option for nickel compounds should not significantly change the total environmental releases of nickel compounds. Therefore, setting an EU-wide OEL for acrylonitrile and nickel compounds will not lead to higher releases in the environment and have no impact. With regard to benzene, lowering the existing OEL at the EU level will even reduce the fugitive or diffuse emissions in some sectors.

Impact on Member States/national authorities

As regards the impact on Member States/national authorities, Member States with established OELs at the level of limit values set in this initiative will be less affected than those having higher or no OEL in place. Although the administrative and enforcement costs will differ from a Member State to another, they should not be significant. Additional administrative costs might be incurred by authorities as regards the necessity to provide information and training to staff, as well as to revise compliance checklists. However, these costs are minor in comparison with the overall costs of functioning incurred by the national enforcement authorities.

Based on the experience gathered from the work of the Senior Labour Inspectors Committee (SLIC) and having regard to the way enforcement activities are organised in different Member States it is unlikely that the introduction of new limit values in the Directive would have any impact on the overall costs of inspection visits. Those are mostly planned independently of the proposal, often following complaints received during a given year and/or according to the inspection strategies defined by a given authority, which may address relevant industries where the concerned chemicals are present. It should also be added that the existence of OELs, by introducing maximum levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks.

Furthermore, this initiative should also contribute to mitigate financial loss of Member State social security and health care systems by preventing ill-health. The benefits for public authorities are even expected to be higher than the costs.

Regulatory fitness and simplification

Impact on SMEs

This proposal does not contain lighter regimes for micro-enterprises or for SMEs. Under the Directive, SMEs are not exonerated from the obligation to eliminate or reduce to a minimum the risks arising from occupational exposure to carcinogens or mutagens.

For many of the carcinogens covered in this initiative, OELs already exist at national level, even if the level as such differs between Member States. Establishing the limit values provided for in this proposal should have no impact on those SMEs situated/located in those Member States where the national limit values are either equal to or lower than the proposed values. However, there will be an economic impact in those Member States (and economic operators established therein) that currently have higher occupational exposure limits established for the carcinogens that are the subject of the proposal.

While companies using acrylonitrile are mainly large companies, SMEs represent a large proportion of the relevant industries dealing with nickel compounds and benzene. For all the substances considered in this initiative, the required investments for SMEs will represent a small share of the SMEs' turnover over the next 60 years. Only a very few number of SMEs concerned by the use of nickel compounds might face some difficulties to comply with the preferred option. For that reason, transitional periods aiming to mitigate the challenges have been included in the package of preferred options.

Impact on EU competitiveness or international trade

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

Although this initiative will result in more stringent OELs compared to some of the European Union's main competitor countries, it should not have a significant impact on the external competitiveness of EU firms. As mentioned above, additional costs per firm are not significant in most cases.

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

Fundamental rights

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

4. BUDGETARY IMPLICATIONS

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

5. OTHER ELEMENTS

Implementation plans and monitoring, evaluation and reporting arrangements

The number of occupational diseases and work-related cancer cases in the EU and the reduction of costs related to occupational cancer for economic operators and social security systems in the EU are the core indicators when monitoring the impacts of this Directive. The monitoring of the first indicator refers to the available data collected by Eurostat, data notified by employers to the competent national authorities in accordance with Article 14 (8) of the Directive and which may be accessed by the Commission in accordance with Article 18 of the Directive, and data submitted by Member States in their national implementation reports in accordance with Article 17a of Directive 89/391/EEC. The monitoring of the second indicator requires the comparison of the estimated data on the burden of occupational cancer in terms of economic loss and health care costs and the data subsequently collected on these matters after the adoption of the revision.

A two-stage compliance assessment (transposition and conformity checks) will be carried out for the transposition of the limit values set. Evaluation of the practical implementation of the proposed amendments will take place in the framework of the periodical evaluation to be carried out by the Commission pursuant to Article 17a of Directive 89/391/EEC. The monitoring of application and enforcement will be undertaken by national authorities, in particular the national labour inspectorates.

At EU level, the SLIC will continue to inform the Commission of any practical problems relating to the enforcement of Directive 2004/37/EC, including difficulties regarding the compliance with binding limit values. Furthermore, SLIC will continue to assess the reported cases, exchange information and good practice in this regard and, if necessary, develop supporting enforcement tools such as guidance.

Explanatory documents (for directives)

Member States must send the Commission the text of national provisions transposing the Directive and a correlation table between those provisions and the Directive. Unambiguous information on the transposition of the new provisions is needed to ensure compliance with the minimum requirements established by the proposal. The estimated additional administrative burden of providing explanatory documents is not disproportionate (it is one off and should not require many organisations to be involved). The explanatory documents can be drafted more efficiently by the Member States.

In view of the above, it is suggested that Member States undertake to notify the Commission of their transposition measures by providing one or more documents explaining the relationship between the components of the Directive and the corresponding parts of national transposition instruments.

Detailed explanation of the specific provisions of the proposal

Article 1

Article 1 states that Directive 2004/37/EC is amended in accordance with the Annex to this Directive. Two new substances are added to Annex III, expanding the list of binding EU limit values, supplemented by a skin notation for acrylonitrile, a notation for dermal and respiratory sensitisation for nickel compounds. The limit value for one existing substance in Annex III, namely benzene, has been updated while its skin notation has been kept. Transitional measures for the three substances have been provided for in the last column of the table.

Article 2 to 4

Articles 2 to 4 contain the usual provisions on transposition into the Member States' national law. In particular, Article 3 refers to the date of entry into force of the Directive.

Annex

The term 'limit value' used in the Annex is defined in Article 2(c) of the Directive. Limit values address the inhalation route of exposure, describing a maximum airborne concentration level for a given chemical agent above which workers should not be exposed, on average, during a defined time period.

A 'skin notation' is assigned for one chemical agent where RAC has assessed that dermal absorption could contribute to the total body burden and consequently to concerns regarding possible health effects, namely acrylonitrile. A skin notation identifies the possibility of significant uptake through the skin. A notation for 'dermal sensitisation' is assigned for one chemical agent where RAC assessed that exposure to it can cause adverse skin reactions, namely nickel compounds. A notation for 'respiratory sensitisation' is assigned for one chemical agent where RAC assessed that exposure to it by inhaling can cause adverse reactions in the respiratory tract, namely nickel compounds. Employers have the obligation to take into account such notations when performing risk assessment and when implementing preventive and protective measures for a particular carcinogen or mutagen in accordance with the Directive.

2020/0262 (COD)

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 EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2004/37/EC of the European Parliament and the Council[3] aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.

(2) Principle 10 of the European Pillar of Social Rights[4], jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens and mutagens at the workplace.

(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values and other directly related provisions should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible.

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1 OJ C , , p. .

2 OJ C , , p. .

3 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) (OJ L 158, 30.4.2004, p. 50).

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

(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.

(5) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and should also be based on a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens.

(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens or mutagens to a shorter reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.

(8) The assessment of health effects of the carcinogens subject to this Directive was based on the relevant scientific expertise from the RAC. Pursuant to a Service Level Agreement signed by DG Employment, Social Affairs and Inclusion and ECHA, RAC provides scientific evaluations on the toxicological profile of each of the selected priority chemical substances in relation to their adverse health effects on workers.

(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council[5] and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen. Acrylonitrile can also be absorbed through the skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring.

(10) With regard to acrylonitrile, a limit value of 1 mg/m³ (0.45 ppm) and a short-term limit value of 4 mg/m³ (1.8 ppm) may be difficult to be complied with in the short term. A

[5] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272.

transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply.

(11) Nickel compounds meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to nickel compounds at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of the nickel compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.

(12) With regard to nickel compounds, limit values of 0.01 mg/m³ for the respirable fraction and 0.05 mg/m³ for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m³ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU[6].

(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.

(14) With regard to benzene, a revised limit value of 0.2 ppm (0.66 mg/m³) may be difficult to be complied with in some sectors in the short term. A transitional period of 4 years after entry into force of this Directive should be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m³) should apply.

(15) The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all priority substances concerned by this Directive, recommended one or several binding occupational exposure limit values for each of them, as well as notations.

(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006[7].

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

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

(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(18) Given that this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.

(19) Directive 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2004/37/EC is amended in accordance with the Annex to this Directive

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [two years] after the date of entry into force of this Directive at the latest. They shall forthwith communicate to the Commission the text of those provisions.

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*