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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

{SWD(2018) 87 final} - {SWD(2018) 88 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Reasons for and objectives of the proposal

This proposal aims to improve workers' health protection by reducing occupational exposure to five carcinogenic chemical agents, to provide more clarity for workers, employers and enforcers, and to contribute to a level playing field for economic operators.

In the State of the Union Address 2017[1] President Juncker emphasized the need to avoid social fragmentation and social dumping in Europe by joining efforts and delivering on the European Pillar on Social Rights.[2] The Pillar - jointly proclaimed by the European Parliament, the Council and the Commission on 17 November 2017 at the Social Summit in Gothenburg - is designed as a compass for a renewed process of convergence towards better working and living conditions across the Union. It identifies workers' right to healthy, safe and well-adapted work environment, which includes protection from carcinogens, as one of the main principles. Protection of workers' health, by continuously reducing occupational exposures to carcinogenic and mutagenic substances, is a concrete action of the Juncker Commission to deliver on this key priority. This has been clearly stated in the Commission Communication on "Safer and Healthier Work for All".[3]

Furthermore, addressing the social dimension of the European Union by putting forward a proposal for a Directive on the protection of workers from health risks in the workplace (related to exposure to carcinogens or mutagens) is included in the Joint Declaration on the EU's legislative priorities for 2018-2019[4].

The intention is also to continue this important work with a view to propose binding limit values for other carcinogens and mutagens.

Cancer is the main work-related health problem in the EU-28, causing almost as much damage to workers' life and health as the two following combined (musculoskeletal disorders and circulatory diseases).[5] However, the negative impact of high exposure to carcinogens and mutagens at the workplace is far more reaching. In addition to cancers, it can also cause a broad range of other significant health problems such as respiratory diseases and neurological disorders. All this brings about suffering to workers and their close ones, poor quality of life, undermined wellbeing and, in the worst case, death.

The European Commission took steps to address these issues by adopting two legislative proposals updating the Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work ("Directive")[6], in May 2016[7]and in

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1 State of the Union Address 2017: https://ec.europa.eu/commission/state-union-2017_en

2 European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

3 Communication from the Commission "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" COM/2017/012 final. http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=2709

4 https://ec.europa.eu/commission/publications/joint-declaration-eus-legislative-priorities-2018_en

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

6 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)

January 2017[8] respectively, addressing together 20 carcinogens. Both proposals were accompanied by relevant Impact Assessments.[9] The first of these proposals was adopted by the co-legislators on 12 December 2017 as Directive (EU) 2017/2398[10] and the second is currently subject to discussion within the Council and the Parliament. The Council reached a general approach at its session on 15-16 June 2017[11], whereas the Parliament's first reading position is expected in the first quarter of 2018.

For the third, present proposal, the Commission conducted in 2017 a two-stage consultation of the European Social Partners,[12] at first on the possible direction of European Union action concerning at first further revisions of the Directive, and secondly on its possible content, in accordance with Article 154 of the Treaty on the Functioning of the European Union (TFEU).

The social partners, workers' and employers' organisations, confirmed that the five following carcinogens selected for the third amendment of the Directive are of high relevance for the protection of workers and encouraged the Commission to continue the preparatory work for the establishment of occupational exposure limit values ("OELs") for:

(1) Cadmium and its inorganic compounds under the scope of the Directive

(2) Beryllium and inorganic beryllium compounds under the scope of the Directive

(3) Arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the Directive

(4) Formaldehyde

(5) 4,4'-Methylene-bis(2-chloroaniline) ("MOCA")[13].

This 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).

Pursuant to Article 16 of the Directive, limit values 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

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7 COM(2016) 248 final of 13 May 2016, 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.

8 COM(2017)11 final of 10 January 2017, 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.

9 SWD(2016) 152 final, http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516268356986&uri=CELEX:52016SC0152 and SWD(2017) 7 final, http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516268483171&uri=CELEX:52017SC0007, respectively.

10 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 (OJ L 345, 27.12.2017, p. 87).

11 Document available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_10438_2017_INIT&from=EN

12 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. 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.

13 The first three carcinogens are substance groups which comprise a large number of priority compounds (Cadmium: 11, Beryllium: 9 and Arsenic: 26 compounds, respectively).

17(1) of the Directive, Annex III to the Directive may be amended in accordance with the procedure laid down in Article 153 (2) of the TFEU (ordinary legislative procedure).

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 this is possible is an integral part of the mechanism for protecting workers[14]. 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[15]. OELs for specific carcinogens or mutagens are set in Annex III to the Directive. Currently, Annex III has fourteen[16] entries.

Reducing exposure to carcinogens and mutagens at the workplace by setting EU-wide OELs effectively contributes to the prevention of cancer cases, as well as other significant non-cancer health problems caused by these substances. Consequently, it improves quality of life and wellbeing of workers and their close ones, prolongs working lives, contributes to better productivity and competitiveness of the EU, and improves the level playing field for businesses within the EU. Estimates show that this proposal, when adopted, in longer term would improve working conditions for over 1 000 000 EU workers and prevent over 22 000 cases of work-related ill-health (cancers and non-cancers) [17].

Available information, including scientific data confirms the need to complete Annex III with occupational exposure limit values for these carcinogenic substances and also confirmed the need to add a skin notation for MOCA, a notation for skin sensitisation for formaldehyde and a notation for skin and respiratory sensitisation for beryllium and its inorganic compounds.[18]

On this basis, it is proposed to take specific measures with a view to establish in Annex III limit values for further five additional carcinogens supplemented by relevant notations, as specified above, in the case of MOCA, formaldehyde and beryllium and its inorganic compounds.

Consistency with existing policy provisions in the policy area

The present initiative for a modification of Directive 2004/37 is in line with the European Pillar of Social Rights. It implements its 10th principle "Healthy, safe and well-adapted work environment" directly contributing to a high level of protection of workers' health and safety.

[14] Article 1 (1) and recital 13 of the Directive.
[15] Article 16 (1) and recital 13 of the Directive.
[16] As amended by Directive (EU) 2017/2398, see footnote 10, above.
[17] RPA (2018) final report. Third study on collecting most recent information for a certain number of substances with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC.
[18] See point 3 on collection and use of expertise.

Modernising the legal framework by setting updated OELs on exposure to carcinogens and mutagens was also identified as the key priority in the occupational safety and health (OSH) field by the Commission Communication "Safer and Healthier Work for All" of 10 January 2017.

Directive 89/391/EEC ("Framework Directive")[19] on health and safety at work and Directive 98/24/EC[20] on risks related to chemical agents at work apply as general law without prejudice to more stringent and/or specific provisions contained in the Directive.

Consistency with other Union policies

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 for a European social triple A rating set 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 growth[21].

The objectives of the proposal are consistent with the fundamental rights as set out in the Charter of Fundamental Rights of the European Union[22], in particular Article 2 (Right to life) and Article 31 (Fair and just working conditions).

Of the five carcinogens considered in this proposal, two substances (arsenic acid and its salts and MOCA[23]) are included in Annex XIV of REACH Regulation[24] and are therefore subject to obtain authorisation before placing on the market or using them. Cadmium has been identified as a substance of very high concern (SVHC) and placed on the candidate list referred to in Article 59(1) of the REACH Regulation for possible inclusion in Annex XIV of REACH. Beryllium and formaldehyde are currently not identified as SVHC nor subject to restrictions under the REACH Regulation. However, concerning formaldehyde the Commission services have requested ECHA to prepare an Annex XV dossier in view of a possible restriction of formaldehyde and formaldehyde releasers in mixtures and articles for consumer uses. In parallel with the preparation of this Annex XV dossier, ECHA is asked to gather existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses.[25]

The Directive and REACH Regulation are complementary. The Framework Directive, which applies as general law to the area covered by this Directive, provides that it applies 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. REACH in turn states that it applies without prejudice to worker protection legislation, including the Directive.

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

[20] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

[21] COM(2010) 2020 and COM(2014) 130 final.

[22] Available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:12016P/TXT

[23] For MOCA the sunset date was 22 November 2017, when it cannot anymore be placed on the market for a use or used after this date, unless an authorisation is issued.

[24] 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.

[25] ECHA website https://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance-rev/18148/term

As regards formaldehyde, Commission Implementing Regulation (EU) 2018/183[26] regulates the specific use of formaldehyde as feed additive, considering that the conditions for an authorisation of that particular use are not fulfilled, in light of the available substitution possibilities together *inter alia* with the application of the precautionary principle.

It is proposed to set forth 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* a*dministrative, 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 limit values and 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.

[26] Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers, OJ L 34, 8.2.2018, p. 6.

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 and mutagens under this proposal[27].

While no EU OELs have yet been established for the five carcinogens considered under this proposed Directive, there is a diverse situation regarding protection at national level. For each substance there is a range of differing national OELs while number of Member States have not yet set national OELs for any of the substances in question[28].

Diverging national OELs lead to different workers protection levels across the EU and also distort competition. Companies operating in one Member State may need to comply with OELs many times lower (i.e. stricter) than companies based in other Member States, and may face increased costs in terms of investments on protective measures/equipment. In addition, these national differences may lead to complications (legal/administrative/organisational) for businesses operating simultanously in different Member States.

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 standards. In all cases, differences in labour standards have an impact on competitiveness, because they impose different costs on operators. This effect on the single market may be reduced through the establishment of clear specific minimum requirements for worker protection in the Member States.

Moreover this proposal will encourage more flexibility in cross-border employment, because workers can be reassured that they will benefit from minimum requirements and levels of protection of their health in all 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 Treaty on European Union (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).

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[27] See Annex 5 to the Impact Assessment enclosed to the proposal which presents an overview of all national OELs in EU Member States for the substances considered under this Directive.

[28] See Table 3 of the Impact Assessment enclosed to the proposal.

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 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 only allows minimum requirements in the field of workers' health and safety protection to be adopted 'by means of directives'.

3. RESULTS OF STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

Stakeholder consultations

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

For this legislative proposal which constitutes the third amendment to the Directive presented by the Juncker Commission, the Commission carried out in the course of 2017 a two-stage consultation of the European social partners pursuant to Article 154(2) of the TFEU, collecting their opinions on the possible direction and content of EU action in this field as regards the establishment and/or revision of further 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.

The three workers' organisations 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 agents in Annex III. Furthermore, they underlined that the number of covered substances must be extended to reach the objective of setting 50 OEL by 2020, according to a list established by the European Trade Union Confederation (ETUC).

The four employers' organisations 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, socio-economic impact assessment and opinion of the tripartite ACSH.

Subsequently, the Commission launched the second phase consultation of the Social Partners. The consultation document considered the possible avenues for EU action to improve workers' protection against carcinogens or mutagens.

The three workers' organisations 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 OEL for carcinogens and mutagens by 2020.

The four employers' organisations 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 OELs for five carcinogens through a third amendment of the Directive.

Consultation of the Advisory Committee on Safety and Health at Work

The ACSH has adopted opinions for all priority substances foreseen by this third amendment of the Directive[29]. It has proposed to complete Annex III with a binding OEL for all of them and in addition relevant notations (skin notation, respiratory and skin sensitisation) for some of them.[30] Moreover, it has highlighted challenges that the practical application of certain OELs could imply in short term.

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" of 10 January 2017, the Commission seeks advice from both the Scientific Committee on Occupational Exposure Limits for Chemical Agents (SCOEL) and the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA)[31]. The Commission may also refer to scientific information sourced elsewhere as long as the data are adequately robust and are in the public domain (e.g. IARC monographs, National Scientific Commitees).

For the substances covered in this initiative, the scientific advice has been provided by SCOEL (on cadmium and its inorganic compounds, beryllium and its inorganic compounds,

[29] The full text of the opinions can be found on CIRCA-BC, https://circabc.europa.eu

[30] See Annex II to the Impact Assessment for summaries of ACSH opinions adopted and proposed OEL values for all substances concerned.

[31] Article 77(3)(c) of 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 (REACH) (OJ L 396, 30.12.2006, p. 1) provides the Commission with a possibility to seek an opinion concerning safety of any substance, including in relation to occupational health and safety.

formaldehyde) and RAC (on arsenic acid and its salts, as well as inorganic arsenic compounds and MOCA).

This is in line with the result of the REACH REFIT exercise[32] focussing on streamlining the process of generating scientific advice. Moreover the Commission Communication on the operation of REACH of 5 March 2018[33] proposes to enhance the role of RAC in delivering scientific opinions for occupational exposure limit values.

In this proposal both committees evaluate the health effects of chemical agents on workers based on sound scientific evidence. They 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 Council Directive 98/24/EC and the Directive.

Impact assessment

This proposal is supported by an impact assessment. The impact assessment report was reviewed by the Regulatory Scrutiny Board and on 23 February 2018 received a positive opinion.[34]

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

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

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, *inter alia* banning the use of the carcinogenic chemical agents; providing industry-specific scientific information and guidelines to support employers in complying with the obligations set by the Directive; proposing market-based instruments such as subsidies, tax breaks or reductions of social insurance contributions to incentivise business to comply with health and safety rules; promoting industry self-regulation, like voluntary product stewardship programmes or autonomous social partner agreements; regulating OELs under other EU instruments (e.g. the REACH Regulation); or directly adopting the most stringent national OEL.

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. Cost and benefits were calculated over a 60-year period, in line with the future cancer burden estimated over the same period, to take proper

[32] REACH REFIT evaluation (REACH Review 2017), more information available at: https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

[33] COM(2018) 116 final

[34] The opinion of the Regulatory Scrutiny Board is available at http://ec.europa.eu/transparency/regdoc/?fuseaction=ia .

account of the cancer latency period. All analytical steps were performed in line with the Better Regulation Guidelines.[35]

The measures resulting from the opinions of ACSH were retained as a policy choice in respect of all the chemical agents in this proposal, including transitional periods for three substances (cadmium, beryllium and arsenic acid). As regards cadmium, immediate adoption of the retained value might negatively affect a very limited number of business units, with some associated job losses. A transition period of seven years as proposed by ACSH[36] would help to mitigate this challenge. Concerning beryllium, the employers' interest group expressed concern that achieving the retained value straightaway might be technically challenging. Therefore, ACSH proposed a transition period of five years[37]. For these substances a transition period with a higher value would make it possible for companies to anticipate the changes, gradually introduce improvements and plan necessary investments, thereby avoiding any closures or job losses. For arsenic acid, the sector which might face technical challenges to implement the retained value as identified by ACSH[38], and consequently would need a transitional period, is copper smelting. 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 concerned substances[39].

As regards the impact on workers, the retained policy option for the five substances under consideration should result in benefits in terms of avoided work-related ill-health and cancer cases and related monetised health benefits, while reducing effects such as suffering of workers and their caring families, a reduced quality of life or undermined wellbeing.

According to estimates, the adoption of the proposal would imply that in the longer term over 1 000 000 EU workers would benefit from improved prevention and protection in relation to occupational exposure to carcinogens and mutagens substances, that can be at the origin of different types of cancers, e.g., lung, bladder, kidney, nasopharyngeal and others, and it would prevent 22 000 cases of ill-health.[40]

As regards the impact on employers, for the majority of carcinogens, costs for businesses are expected to be limited to minor adjustments that will need to be done in specific cases to ensure full compliance. The proposal does not add information obligations and will thus not lead to an increase in administrative burdens on enterprises. 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.

As regards the impact on Member States/national authorities, given the substantial economic costs of workers' exposure to hazardous substances, this proposal would also

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

[36] ACSH, 2017: Opinion on an EU Occupational Exposure Limit value for Cadmium and its inorganic compounds under Directive 2004/37/EC (CMD), available at: https://circabc.europa.eu/sd/a/937cca1a-c6ff-4a17-9d8a-6c7aa00107a9/Doc.663-17-EN_WPC%20Opinion%20Cadmium_Adopted%2031.05.2017%20.pdf

[37] ACSH, 2017: Opinion on an EU Occupational Exposure Limit value for Beryllium and its inorganic compounds under Directive 2004/37/EC (CMD), available at: https://circabc.europa.eu/sd/a/2d61770f-7b5d-45bc-b2b4-4c8460e78c93/Doc.662-17-EN_WPC_Opinion%20on%20Be_Adopted%2031.05.2017.pdf

[38] ACSH, 2017: Opinion on an EU Occupational Exposure Limit value for Arsenic acid and its salts as well as inorganic arsenic compounds in the scope of Directive 2004/37/EC (CMD), available at: https://circabc.europa.eu/sd/a/9813acc5-604a-49f9-9d4b-afaeceb12705/Doc.1334_01_EN_WPC_Opinion%20Arsenic_Adopted%2019102017.pdf

[39] See footnote 17, above.

[40] See footnote 17, above.

contribute to mitigating financial losses sustained by Member States' social security systems. From an economic point of view, the coverage and adequacy of EU-wide limit values is the single most important determinant of who bears the cost burden of occupational ill-health.

Administrative and enforcement costs for Member States will differ according to the present status of each chemical agent in each Member State, but should not be significant. Furthermore, the establishment of OELs at EU level may reduce in some Member States the need to conduct a separate evaluation on each carcinogen thereby removing an inefficiency of repetition of identical tasks.

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.

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.

From the comparison of the options and the analysis of costs and benefits, it can be concluded that the proposal achieves the objectives set at overall reasonable costs and is appropriate.

Increased releases to the environment are not expected from the application of lower OELs therefore the proposal does not have significant environmental impacts.

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.

For the majority of carcinogens, the impact on operating costs for business (including SMEs) will be limited as only minimal adjustments will be needed to ensure full compliance. This proposal will not add information obligations or lead to an increase in administrative burdens on firms. Furthermore, transition periods established for some of the substances will help

SMEs to address any specific technical challenges and plan investments sufficiently in advance.

Impact on EU competitiveness or international trade

Risk prevention and the promotion of safer and healthier conditions in the workplace are key, not just to improving working conditions and job quality but also to promoting competitiveness. Keeping workers healthy has a direct and measurable positive impact on productivity, and contributes to improving the sustainability of social security systems. Implementing the provisions of this proposal would have a positive impact on competition within the single market. Competitive differences between firms located in Member States with different national limit values may be reduced through the establishment of EU-wide limit values for those agents.

The proposal should not have a significant impact on the external competitiveness of EU firms. While non-EU countries have established a wide range of exposure values, the retained limit values are not out of line with international practice (e.g., US, Canada, Japan, South Korea and Australia).

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

Monitoring of the number of occupational diseases and related occupational cancer cases using the available data sources is foreseen[41], as well as monitoring of costs related to occupational cancer for economic operators (e.g. loss of productivity) and social security systems.

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 17(a)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 Committee of Senior Labour Inspectors (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.

[41] These include data that could be collected by Eurostat on occupational diseases, as well as on other non-cancer work-related health problems and illnesses in accordance with Regulation (EC) No 1338/2008, data submitted by Member States in the national reports on the implementation of EU occupational health and safety *acquis*, submitted in accordance with Article 17(a) of Directive 89/391/EEC and data notified by employers to the competent national authorities on cases of cancer identified in accordance with national law and/or practice as resulting from occupational exposure to a carcinogen or mutagen in accordance with Article 14(8) of Directive 2004/37/EC, and which may be accessed by the Commission in accordance with Article 18 of Directive 2004/37/EC.

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

Five new substances are added to Annex III, expanding the list of binding EU limit values, supplemented by a skin notation for MOCA, a notation for skin sensitisation for formaldehyde, and a notation for skin and respiratory sensitisation for beryllium and its inorganic compounds.

Articles 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 substantially to the total body burden and consequently to concerns regarding possible health effects, namely MOCA. A skin notation identifies the possibility of significant uptake through the skin. A notation for 'skin sensitisation' is assigned for two chemical agents where the SCOEL assessed that exposure to them can cause adverse skin reactions, namely formaldehyde and beryllium and its inorganic compounds. A notation for 'respiratory sensitisation' is assigned for one chemical agent where the SCOEL assessed that exposure to it by inhaling can cause adverse reactions in the respiratory tract, namely beryllium and its inorganic 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.

2018/0081 (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[42],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Principle 10 of the European Pillar of Social Rights[43], proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to healthy, safe and well-adapted work environment. The right to a high level of protection of the health and safety at work, as well as to a working environment adapted to the professional needs of workers and which enables them to prolong their participation in the labour market includes also protection from carcinogens and mutagens at the workplace.

(2) Directive 2004/37/EC of the European Parliament and of the Council[44] 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 carcinogens and mutagens is provided for in Directive 2004/37/EC by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. Binding occupational exposure limit values established on the basis of available information, including scientific and technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace, are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. The minimum requirements provided for in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States.

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42 OJ C ,, p.

43 European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

44 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).

(3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other obligations of employers 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. In that context, it is essential to take the precautionary principle into account where there are uncertainties.

(4) For most carcinogens and mutagens, it is not scientifically possible to identify levels below which exposure would not lead to adverse effects. While setting the limit values at the workplace in relation to carcinogens and mutagens pursuant to Directive 2004/37/EC does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure in the stepwise and goal-setting approach pursuant to Directive 2004/37/EC. For other carcinogens and mutagens, it may be scientifically possible to identify levels below which exposure is not expected to lead to adverse effects.

(5) Maximum levels for the exposure of workers to some carcinogens or mutagens are established by values which, pursuant to Directive 2004/37/EC, must not be exceeded.

(6) 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 evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and 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. Transparency of such information should be further encouraged.

(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. Amendments to Annex III to Directive 2004/37/EC provided for in this Directive constitute a further step in a longer term process initiated to update Directive 2004/37/EC.

(8) The assessment of health effects of carcinogens subject to this proposal was based on the relevant scientific expertise from the SCOEL and the RAC.

(9) SCOEL, the activities of which are regulated by the Commission Decision 2014/113/EU[45] assists the Commission, in particular in identifying, evaluating and analysing in detail the latest available scientific data, and in proposing occupational exposure limit values for the protection of workers from chemical risks, which are to

[45] Commission Decision of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 4.3.2014, p. 18)

be set at Union level pursuant to Council Directive 98/24/EC[46]and Directive 2004/37/EC.

(10) Pursuant to Regulation EC No 1907/2006 of the European Parliament and of the Council[47] RAC delivers opinions of ECHA related to the risks of chemical substances to human health and the environment. In the context of this proposal, RAC delivered its opinion as requested in accordance with Article 77(3)(c) of Regulation EC No 1907/2006 of the European Parliament and of the Council.

(11) Cadmium and many of its inorganic compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is appropriate, on the basis of available information, including scientific and technical data, to set a limit value for that group of carcinogens. It is therefore appropriate to establish a limit value for cadmium and its inorganic compounds under the scope of Directive 2004/37/EC. In addition, cadmium, cadmium nitrate, cadmium hydroxide and cadmium carbonate were identified as substances of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and are included in the candidate list referred to in Article 59(1) of that Regulation for authorisation under the REACH Regulation.

(12) With regard to cadmium, a limit value of 0,001 mg/m^3 may be difficult to be complied with in some sectors in the short term. A transitional period of seven years should therefore be introduced during which the limit value 0,004 mg/m^3 should apply.

(13) Beryllium and most inorganic beryllium compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. In addition to carcinogenic properties beryllium is known to provoke chronic beryllium disease (CBD) and beryllium sensitisation (BeS). It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that group of carcinogens. It is therefore appropriate to establish a limit value for beryllium and inorganic beryllium compounds under the scope of Directive2004/37/EC and to assign a notation for skin and respiratory sensitisation.

(14) With regard to beryllium, a limit value of 0,0002 mg/m^3 may be difficult to be complied with in some sectors in the short term. A transitional period of five years should therefore be introduced during which the limit value of 0,0006 mg/m^{3}should apply.

(15) Arsenic acid and its salts, as well as most inorganic arsenic 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 appropriate, on the basis of the available information, including scientific and technical data, to set a limit value for that group of carcinogens. It is therefore appropriate to establish a limit value for arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of Directive 2004/37/EC. In addition,

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46 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

47 Article 77(3)(c) of 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 (REACH) (OJ L 396, 30.12.2006, p. 1) provides the Commission with a possibility to seek an opinion concerning safety of any substance, including in relation to occupational health and safety.

arsenic acid, diarsenic pentaoxide and diarsenic trioxide are identified as substances of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and are included in Annex XIV to that Regulation, requiring authorisation before they can be used.

(16) With regard to arsenic acid, a limit value of 0,01 mg/m^3 may be difficult to be complied with in the copper smelting sector and therefore a transitional period of two years should be introduced.

(17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. 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. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses[48].

(18) 4,4'-Methylene-bis(2-chloroaniline)(MOCA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign to it a skin notation. In addition, it was identified as a substance of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA.

(19) The Commission has consulted the ACSH. It has also 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. ACSH has adopted opinions for all priority substances foreseen by the present proposal and proposed a binding occupational exposure limit value for each of them, supporting the relevant notations for some of them[49].

(20) This Directive respects fundamental rights and observes the principles enshrined in the Charter of Fundamental Rights of the European Union, in particular the right to life and the right to fair and just working conditions provided for, respectively, in Articles 2 and 31 thereof.

(21) The limit values set out in this Directive are to be kept under review to ensure consistency with Regulation (EC) No 1907/2006 of the European Parliament and of the Council [50], in particular to take account of the interaction between limit values set

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48 https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e

49 The full text of the opinions can be found on CIRCA-BC, https://circabc.europa.eu

50 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 (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

out under Directive 2004/37/EC and derived no effect levels for hazardous chemicals under that Regulation in order to protect workers effectively.

(22) Since the objectives of this Directive, which are to improve working conditions and to protect the health of workers from the specific risks arising from exposure to carcinogens and mutagens, 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 those objectives.

(23) In implementing this Directive Member States should avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, and to publish the results of such assessments.

(24) As 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.

(25) 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…][51]. They shall immediately inform the Commission of the text of those measures.

   When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the measures 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*.

[51] Two year after the entry into force of this Directive.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

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