EUROPEAN
COMMISSION

Brussels, 10.1.2017
COM(2017) 11 final

2017/0004 (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

(Text with EEA relevance)

{SWD(2017) 7 final}
{SWD(2017) 8 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 carcinogenic chemical agents, to provide more clarity and to contribute to a level playing field for economic operators. It is among the priority actions identified in the Commission Work Programme for 2016. With this initiative the Commission delivers on its commitment to improve the efficiency and effectiveness of the EU framework for protecting workers. The intention is also to continue this important work and to conduct further impact assessments with a view to propose limit values for additional carcinogens.

Estimates of the recent and future burden of occupational diseases indicate that work-related cancer is a problem and will remain so in the future as a result of exposure of workers to carcinogens. Cancer is the first cause of work-related deaths in the EU. Annually, 53 % of occupational deaths are attributed to cancer[1]. According to a 2016 report by the Netherlands National Institute for Public Health and the Environment (RIVM)[2] 91,500-150,500 people were newly diagnosed with cancer in 2012, caused by past exposure to carcinogenic substances at work. Between 57,700 – 106,500 people died in 2012 as a result of a work-related cancer. That means that every hour in EU, between 7-12 people die of cancer because of past exposure to carcinogenic substances at work.

The Commission took a first step to address these issues by adopting on 13 May 2016 a legislative proposal to amend Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work ('the Directive')[3] with a view to revise or to introduce exposure limit values for 13 chemical agents[4]. In accordance with Article 16 of the Directive, the Council shall set such limit values 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. Pursuant to Article 17 (1) of the Directive, Annex I and III to the Directive may be amended in accordance only with the procedure laid down in Article 153 (2) of the Treaty on the Functioning of the European Union ('TFEU') (ordinary legislative procedure).

The Commission is now taking a further step in a longer-term process of updating the Directive with regard to 7 more carcinogens and proposes to establish limit values and/or skin notations. According to the impact assessment this is estimated to result in increased protection for at least 4 million workers and improved clarity for employers and enforcers. Together it is estimated that both proposals would prevent over 100,000 deaths caused by work-related cancer.

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

[2] Work-related cancer in the European Union: Size, impact and options for further prevention, http://rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/mei/Work_related_cancer_in_the_European_Union_Size_impact_and_options_for_further_prevention , p. 11.

[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) (codified version) (Text with EEA relevance) (OJ L 158, 30.4.2004, p. 50).

[4] COM(2016)248. This proposal was accompanied by an impact assessment (IA) (SWD(2016)152).

In accordance with Article 16 of the Directive, the Commission pursues its work to set further limit values and additional chemical agents are currently under assessement with a view to a future amendment of the Directive.

The provisions of the Directive apply to any chemical agent that meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008 (CLP)[5]. This Regulation lists 'harmonised' (mandatory) classifications for 1017 chemical substances as Category 1 carcinogens ('known or presumed human carcinogens') on the basis of epidemiological and/or animal data.[6] Another important classification process, by the International Agency for Research on Cancer ('IARC'), has identified nearly 500 agents that are carcinogenic for humans (Group 1; 118 agents), probably carcinogenic to humans (Group 2A; 75) or possibly carcinogenic to humans (Group 2B; 288)[7].

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

The Directive sets a number of general minimum requirements to eliminate or reduce exposure for all carcinogens and mutagens falling under its scope. Employers must identify and assess risks to workers associated with exposure to specific carcinogens (and mutagens) 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 occupational exposure limit values for the inhalation route of exposure for particular carcinogens and mutagens is an integral part of the mechanism for protecting workers[8]. 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[9]. Occupational exposure limit values for specific carcinogens or mutagens are set in Annex III to the Directive. Currently, Annex III has three entries.

Occupational exposure limit values set under the Directive should, when appropriate, be revised to take into account new scientific data, improvements in measurement techniques, risk management measures and other relevant factors.

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[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

[6] According to that Regulation, 1017 chemical agents (and groups of chemical agents) have received mandatory 'harmonised classification' as 'category 1' carcinogens, attracting the label hazard statement 'may cause cancer'.

[7] Monographs on the evaluation of carcinogenic risk to humans, International Agency for Research on Cancer, WHO.

[8] Article 1 (1) and recital 13 of the Directive.

[9] Recital 13 of the Directive.

On this basis, it is proposed to take two specific measures:

(a) Include in Annex I to the Directive work involving exposure to oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine and establish a corresponding skin notation in Part B of Annex III to the Directive

The International Agency for Research on Cancer ('IARC') assessed the carcinogenicity of "mineral oils" in 1983[10] and 1987[11] and concluded that there is *sufficient evidence* from studies in *humans* that mineral oils (containing various additives and impurities) that have been used in occupations such as mulespinning, metal machining and jute processing are carcinogenic to humans. This IARC assessment also covers mineral oils that have been used in engines. The final IARC evaluation does not explicitly mention "mineral oils as used engine oils", but concludes that there is sufficient evidence from studies in humans that "untreated and mildly treated mineral oils" are carcinogenic to humans (IARC Group 1). IARC reviewed the assessment based on new data in Monograph 100F (2012)[12] and maintained that categorization in relation to skin cancer. The Scientific Committee on Occupational Exposure Limits ('SCOEL')[13] evaluated the health effects on workers at work of "mineral oils as used engine oils", defined as "oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine" (hereinafter, "mineral oils as used engine oils"). Taking into consideration the IARC assessment, SCOEL, in accordance with its methodology, concluded that "mineral oils as used engine oils" are carcinogenic group A with no indication for a mode of action-based threshold[14].

The skin notation to be set out in Part B of Annex III proposed in this initiative was strongly recommended by SCOEL, which assessed that occupational exposure to mineral oils as used engine oils occurs through the dermal route. The notation, which indicates the possibility of significant dermal uptake, was agreed by the Advisory Committee on Safety and Health at Work ('ACSH').

Mineral oils as used engine oils are not placed on the market as such, but are process-generated, and therefore they are not classified in accordance with Regulation (EC) No 1272/2008. However, the Directive makes provisions for the inclusion in Annex I of substances or mixtures or processes as well as substances or mixtures released by a process referred to in that Annex which, although not subject to the classification obligation in accordance with the said Regulation, meet the criteria for classification as a carcinogen. Mineral oils as used engine oils fall within this category.

(b) Establish in Annex III limit values supplemented by skin notations for further 5 additional carcinogens, as well as skin notations independently of limit values for 2 carcinogens, including for mineral oils as used engine oils.

Available information, including scientific data confirms the need to complete Annex III with limit values supplemented by skin notations for 5 additional carcinogens. SCOEL submitted

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[10] IARC (1984), Polynuclear aromatic hydrocarbons, Part 2, carbon blacks, mineral oils (lubricant base oils and derived products) and some nitroarenes. IARC Monogr Eval Carcinog Risk Chem Hum, 33: 1–222. PMID:6590450 (http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono33.pdf).

[11] IARC (1987). Overall evaluations of carcinogenicity: an updating of IARC Monographs volumes 1 to 42. IARC Monogr Eval Carcinog Risks Hum Suppl, 7: 1–440. PMID:3482203.

[12] IARC (2012), (http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F.pdf).

[13] Commission Decision 2014/113/EU 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).

[14] SCOEL/OPIN/2016-405, Mineral Oils as Used Engine Oils, adopted on 9 June 2016.

recommendations for these carcinogens. For 2 carcinogens[15], SCOEL identified the possibility of significant dermal uptake and recommended the establishment of skin notations.The ACSH was consulted on all aspects of this proposal, in accordance with Article 2(2)(f) of the Council Decision of 22 July 2003[16]. With regard to the values proposed, socio-economic feasibility factors have been taken into account further to the consultation of the ACSH.

- **Consistency with existing policy provisions in the policy area**

The Commission has as strategic goal to ensure a safe and healthy work environment for workers in the EU according to its Communication on the EU Strategic Framework on Health and Safety at Work 2014 – 2020[17]. One of the main challenges identified in the strategic framework is to improve the prevention of work-related diseases by tackling existing, new and emerging risks.

This initiative fits within the Commission's priority for a deeper and fairer single market, in particular its social dimension. It is in line with Commission's work to establish a fair and truly pan-European labour market that provides workers with decent protection and sustainable jobs[18]. This includes occupational health and safety protection, social protection, and rights connected to the employment contract.

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].

Of the 7 carcinogens considered in this proposal, three have been added to the candidate list of identified 'substances of very high concern' (SVHCs) established under Article 59(1) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') and subsequently included in Annex XIV to REACH

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[15] Polycyclic aromatic hydrocarbons mixtures containing benzo[*a*]pyrene which are carcinogens as defined in the Directive; mineral oils as used engine oils..

[16] Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work, OJ C 218, 13/09/2003, p. 0001 - 0004

[17] COM (2014) 332 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN

[18] President Juncker's State of the Union address in the European Parliament on 9 September 2015 (https://ec.europa.eu/priorities/sites/beta-political/files/state_of_the_union_2015_en.pdf)

[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.

for authorisation purpose: ethylene dichloride (EDC); 4,4'-Methylenedianiline (MDA) and trichloroethylene (TCE).

Benzo[*a*]pyrene has recently been included in the candidate list of identified SVHC for authorisation. As a member of the group 'polycyclic aromatic hydrocarbons' (PAHs), benzo[*a*]pyrene is also listed in Annex XVII to REACH (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles) with regard to the placing on the market of extender oils or their use in the production of tyres or part of tyres above a certain concentration.

The Directive and REACH are legally complementary. The Framework Directive, which applies as general law to the area covered by the 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.

In the context of the complementary operation of the Directive and REACH, it is proposed to set forth limit values under the Directive for the following reasons:

– Mineral oils as used engine oils and polycyclic aromatic hydrocarbons mixtures containing benzo[*a*]pyrene which are carcinogens as defined in Directive 2004/37/EC[22] and are process generated are outside the scope of REACH;

– Among the three carcinogens included in the present proposal that are also subject to authorisation under REACH, two are mainly used as intermediates[23], i.e. manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. As such, these are exempted from the authorization requirement. However, occupational exposure to intermediates could occur for example during cleaning, maintenance, sampling etc., where residues may be present and/or where process-streams are interrupted and containment may be compromised.

– For ethylene dibromide, the Risk Management Option Analysis (RMOA) of 16 July 2015 came to the conclusion, that while the substance could be proposed to be identified as a substance of very high concern to be included in the candidate list for potential prioritisation to Annex XIV to REACH, the European Commission considers that it is more appropriate to address the main non-intermediate use of the substance, i.e. additive in leaded aviation gasoline, at international level and/or under other EU legislation than REACH.

– Limit values are an important part of the Directive and of the wider occupational safety and health approach to managing chemical risks.

– The Directive covers every use of a chemical agent at the workplace through its entire lifecycle, and covers worker exposure to carcinogenic agents released by *any*

[22] Complex polycyclic aromatic hydrocarbon mixtures (PAH) containing benzo[a]pyrene or low molecular weight PAH mixtures, are not produced and used as such, but are specifically and ubiquitously formed during combustion and pyrolysis processes of organic materials (see in this sense, final draft Recommendation from the Scientific Committee on Occupational Exposure Limits for Polycyclic Aromatic Hydrocarbon Mixtures containing benzo[a]pyrene (PAH), No. 404.

[23] In the case of ethylene dichloride, more than 95% of the total volume is use as an intermediate on site in the synthesis of vinyl chloride monomer; 4,4'-Methylenedianiline is mostly (99%) used as an intermediate in the production of 4,4'-methylenediphenyldiisocyanate (MDI), which is used in the production of polyurethane foams; approximately 75% of the total production of trichloroethylene, as assessed in the IOM Study, was used in intermediate applications.

work activity, whether produced intentionally or not, and whether available on the market or not.

– Occupational exposure limit values for carcinogens are set via a robust process – ultimately passing through the co-legislator for adoption – based on available information, including scientific and technical data and stakeholder consultation.

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. On that basis, Article 16 of Directive 2004/37/EC provides for the adoption of limit values in accordance with the procedure laid down in Article 153(2) 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, by including in Annex I to the Directive 2004/37/EC mineral oils as used engine oils, by setting limit values supplemented by skin notations for 5 additional carcinogens and by establishing skin notations (independently of limit values) for 2 additional carcinogens, including for mineral oils as used engine oils. This is achieved through the establishment of additional minimum requirements for workers' health protection in the form of limit values and/or skin 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[24]. Some Member

[24] See Table 1 in Annex 7 in the impact assessment. See also Annex 10, presenting for each chemical agent in graphs, the current national occupational exposure limit values versus the preferred option (option 2) used for the limit values put forward in this proposal.

States have already established binding limit values that are at the same value or lower than the value recommended by the ACSH[25]. This demonstrates that unilateral national action is possible as regards setting a limit value for these chemical agents. However, there are also many cases where Member States have no limit values or ones that are less protective of worker health than the value put forward in this proposal. In addition, where national limit values exist, they vary considerably, leading to different levels of protection[26]. Some of these limits are considerably higher than the ones being proposed.

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. The proportion of potentially exposed workers who lack such legal protection was taken into account in the analysis of impacts of introducing a limit value for each of the considered carcinogens. In that framework, a subsidiarity and proportionality check was carried out for each specific agent, which indicated that, where relevant data were available, introduction of proposed limit values would improve legal protection for an estimated 69% to 82% of exposed workers[27].

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.

Absent or too high limit values also provide potential incentive for companies to locate their production facilities in Member States with the lower standards, thus impacting the cost of production. 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 enjoy minimum requirements and levels of protection of their health in all the Member States.

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 long and intensive discussions with all stakeholders (representatives of employees' associations, representatives of employers' associations, 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 2 in Annex 7 in the impact assessment for national limit values in the Member States compared to levels recommended by the ACSH.

[26] For example for ethylene dibromide, the values range from 0.002 to 145 mg/m^3. For ethylene dichloride, values range from 4 to 412 mg/m^3. For trichloroethylene, values range from 3.3 to 550 mg/m^3.

[27] See Table 4 in annex 7 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

An independent ex-post evaluation of the Directive (as part of the overall occupational health and safety acquis) has recently been concluded. Apart from the interface between the REACH Regulation and the Directive, the key issues identified in that evaluation are outside the scope of the proposal, which addresses specifically the technical amendment of Annexes to the Directive rather than broader policy questions regarding its operation or relevance.

- **Stakeholder consultations**

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

For this legislative proposal in the field of social policy, the Commission carried out a two-stage consultation of the European social partners in accordance with Article 154 of the TFEU.

The first stage of consultation on the protection of workers from risks related to exposure to carcinogens, mutagens and chemical agents toxic for reproduction at work was launched on 6 April 2004.

In accordance with Article 154(2) of the TFEU, the social partners were asked to give their opinions on the possible direction of EU action in this field. This first phase confirmed that action needs to be taken at EU level to introduce better standards across the EU, and to tackle situations involving workers' exposure. All the European social partners who replied to the consultation[28] underlined the importance they attached to protecting workers from the health risks in this area.

[28] Union of Industrial and Employers' Confederations of Europe (UNICE), European Centre of Enterprises with Public Participation and of Enterprises of General Economic Interest (CEEP), European Association of Craft, Small and Medium-Sized Enterprises (UEAPME), European Trade Union Confederation (ETUC), European Confederation of Executives and Managerial Staff (CEC), Confederation of National Associations of Tanners and Dressers of the European Community (COTANCE), European Trade Association of Hotels, Restaurants and Cafés in Europe (HOTREC), European Federation of Trade Unions in the Food, Agriculture and Tourism Sectors and Allied Branches (EFFAT), Union Network International — Europe Hair & Beauty (UNI-Europa Hair&Beauty).

However, while all respondents acknowledged the relevance of existing legislation, their views differed as to the strategy and direction of future action and which factors should be taken into consideration[29].

The second stage of consultation was launched on 16 April 2007 in accordance with Article 154(3) of the TFEU on the content of the proposal.

The specific points for consultation were:

- including chemical agents toxic for reproduction (categories 1A and 1B) in the scope of Directive 2004/37/EC;
- updating limit values for chemical agents in Annex III of Directive 2004/37/EC;
- including limit values for more chemical agents in Annex III of Directive 2004/37/EC;
- introducing criteria for setting limit values for carcinogens and mutagens;
- focusing on training and information requirements.

The Commission received replies from seven European social partner organisations[30]. In their replies these organisations reaffirmed their approach to the prevention of occupational risks derived from carcinogens and mutagens at work, as outlined in their responses to the first stage consultation.

The responses gathered can be summarized as follows:

- **there were no significant divergences** on the methodologies to be used and the criteria to be set up for the derivation of limit values. The introduction of criteria for limit values setting was seen as generally positive. However, socio-economic impact assessments and the consideration of feasibility factors should be part of the criteria. Social partners expressed the view that the ACSH should play an important role in the setting of limit values.
- **there was an overall agreement** on the need for effective implementation of training and information requirements, an issue considered to be a key aspect of the prevention policy.
- **the revision of binding limit values** should be examined in the light of the implementation of REACH and of the relationship and interaction between limit values and DNELs (Derived No Effect Levels) derived under REACH for hazardous chemicals.

While the formal social partners consultation process was completed in 2007, the following ACSH consultation described below, where social partners were present alongside Member States representatives, ensured that the social partners were duly informed about options for limit values and actively participated in identifying the preferred ones.

[29] CISNET EMPL 8676 of 15 June 2006.

[30] Four from employers' organisations (Business Europe, Eurocommerce, European Association of Craft Small and Medium-sized Enterprises (UEAPME) and European Cement Industry), two from workers' organisations (European Trade Union Confederation (ETUC), and European Federation of Building and Woodworkers (EFBWW)) and one from an independent organisation (British Occupational Hygiene Society (BOHS)).

In the final stages of the preparatory process, the Commission organised a meeting on 14 October 2016 with the social partners to present the envisaged scope and approach for the draft Directive. This built on the two-stage consultations and the detailed discussions, which have been undertaken in the context of the ACSH on specific substances and limit values to be inserted in the annexes of the Directive.

Consultation of the ACSH – through the tripartite Working Party 'Chemicals at the Workplace' (WPCs)

Following the social partners consultation, the Commission informed the members of the WPCs at its meeting in April 2008 on its intention to propose a revision of the Directive. An in-depth discussion on the results of the study contracted by the Commission ('IOM study'[31]) based on draft reports for individual chemical agents took place at the meeting in March 2011. The discussions on the individual chemical agents took place at various meetings of the WPCs in 2011[32], 2012[33] and 2013[34], resulting in one opinion and two supplementary opinions adopted by the plenary of the ACSH in 2012[35] and 2013[36,37] completed with further discussions in the meetings of the WPCs. These discussions took into account the available information, including the scientific data (that is to say, SCOEL Recommendations, as well as scientific information sourced elsewhere adequately robust and in the public domain).

The consultation process results included support for the following[38]:

- to bring a limited number of process generated substances under the scope of the Directive by including them in Annex I;
- to revise existing limit values in Annex III in the light of the most recent scientific data, and to add additional limit values for a limited number of substances in Annex III where available information, including scientific and technical data, supports this.

The limit values agreed upon by the ACSH were taken up in this proposal.

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[31] IOM Research Project P937/99, May 2011 – Health, social-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work.

[32] Meeting of the WPCs on 23 March 2011; Meeting of the WPCs on 15 June 2011; Meeting of the WPCs on 26 October 2011.

[33] Meeting of the WPCs on 21 March 2012; Meeting of the WPCs on 6 June 2012; Meeting of the WPCs on 21 November 2012.

[34] Meeting of the WPCs on 6 March 2013; Meeting of the WPCs on 19 June 2013; Meeting of the WPCs on 2 October 2013.

[35] Opinion on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace. Adopted on 05/12/2012 (Doc. 2011/12).

[36] Supplementary opinion on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace. Adopted on 30/05/2013 (Doc. 727/13).

[37] Supplementary opinion No. 2 on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace. Adopted on 28/11/2013 (Doc. 2016/13).

[38] The three adopted ACSH opinions include, where necessary, specific comments from the interest groups (the social partners and Member States) which broadly reflect the principal points maintained by each interest group throughout discussions of the Working Party 'Chemicals at the Workplace' (WPCs). In many cases there are no specific comments as there was a consensus view of the three interest groups. As such the final ACSH Opinions should be taken as representative of the views of stakeholder groups represented.

Meetings with the industry and the workers' representatives

From 2013 to 2015, a number of meetings took place between the Commission services and industry and workers representatives concerned about specific chemical agents subject to the initiative[39]. The main purpose of the meetings requested by industry was to obtain information on the process for amending the legislation in general and on the intention of the Commission with regard to the proposed value for particular chemical agents.

- **Collection and use of expertise**

In reviewing or setting new limit values under the Directive, a specific procedure is followed. It involves seeking scientific advice (e.g. SCOEL, National Scientific Committee) and consulting the ACSH. The Commission can 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 or conclusions from scientific committees setting national limit values).

SCOEL[40] evaluates the health effects of chemical agents on workers at work. The work of SCOEL directly supports EU regulatory activity in the field of occupational safety and health. It develops high quality comparative analytical knowledge and it ensures that Commission proposals, decisions and policy relating to the protection of workers' health and safety are based on sound scientific evidence. SCOEL assists the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at EU level pursuant to Council Directive 98/24/EC and the Directive.

For the purpose of this initiative, the Commission services have used the relevant chemical agent-related SCOEL recommendations where available (these are published on the internet[41]) as well as scientific information sourced elsewhere adequately robust and in the public domain. In that regard, for ethylene dibromide and epichlorohydrine, discussions in the ACSH took place on the basis in particular of the relevant SCOEL Recommendations and of conclusions from scientific committees setting national limit values.

Following the two stage consultation of the European social partners, the Commission's Directorate-General for Employment and Social Affairs published on 25 July 2008 an open call for tender. 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 carcinogenic chemical agents at the workplace. The resulting IOM study contained full reports on 25 carcinogenic chemical agents, including the 7 referred to in this proposal. The outcome of this study (summary report and individual chemical agents' reports) provides the main basis for the impact assessment for this proposal[42].

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[39] See section 9.2.6 of the impact assessment. The Commission also participated in meetings organised annually by Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs with the European Glass and Ceramic Industry.

[40] Commission Decision 2014/113/EU 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, 04.03.2014, p. 18).

[41] https://circabc.europa.eu.

[42] The following links are only provided for those chemical agents subject to the second amendment of the Directive:
- Executive summary report
- Summary report

- **Impact assessment**

This proposal is supported by an impact assessment. The impact assessment report was reviewed by the Regulatory Scrutiny Board and on 28 October 2016 received a positive opinion with reservations[43].

The following options for different limit values and/or skin notations for each of the 7 carcinogens were examined:

- A baseline scenario of no further EU action for each chemical agent in this initiative (option 1).
- The adoption of the values agreed by the ACSH (option 2). As already indicated, for each of the 7 chemical agents, the scientific and technical data has been considered at the ACSH, resulting in their opinions of the ACSH on limit values and/or skin notations to be proposed.
- Where appropriate and depending on specific characteristics of the agents, flanking options to either propose a limit value which, compared with the ACSH value, is lower (theoretically more protective of worker health) or higher (theoretically less protective of worker health) were also examined as option 3 and/or 4 respectively, for some of the chemical agent. These flanking values were drawn from the IOM study, for which they were established by preference:

  i) from the SCOEL recommendation where available;
  ii) as values reflecting available data (for example taking account of existing limit values in the Member State) or;
  iii) on the basis of recommendations from the contractor (for example taking into account non-EU limit values). Where available data did not support setting a lower or higher limit value than the ACSH value, these options were discounted.

Other policy options, such as introducing a ban on the use of the chemical agents, self-regulation, market-based instruments, providing industry-specific information scientific information without amending the Directive, regulating under REACH, guidance and other implementation support for the Directive have also been considered. As regards the interface between REACH and the Directive, the General Court of the EU recently clarified in a case currently under appeal[44] the meaning of the first set of the conditions set out in Article 58(2) of REACH for the granting of an exemption to uses or categories of uses from the authorisation requirement – i.e. *specific EU legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance* - as

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- Trichloroethylene
- 4,4'-Methylenedianiline
- Epichlorohydrine
- Ethylenedibromide
- Ethylene dichloride
- Polycyclic aromatic hydrocarbons mixtures
- Mineral oils as used engine oils

[43] The opinion of the Regulatory Scrutiny Board is available at http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2016_en.htm

[44] On 25 September 2015 the General Court of the EU issued its Judgment on Case T-360/13, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) v European Commission*. The case is currently under appeal, Case C-651/15 P.

applied to a number of EU Directives, including Directive 2004/37/EC. The General Court of the EU held that in so far as Directive 2004/37/EC does not refer to any substance other than benzene, vinyl chloride monomer or hardwood dusts, for which it lays down maximum values for occupational exposure, it cannot be considered either 'specific' or to impose 'minimum requirements', within the meaning of Article 58(2) of REACH.

Furthermore, the concerned Commission services are collaborating with stakeholders in their relevant policy and technical fields with regard to the relationship between REACH and occupational health and safety chemicals directives and will develop guidance on this. The Commission services, Member States, and the social partners have all expressed their view that occupational health and safety directives are the appropriate EU legislative framework to establish minimum requirements in the form of occupational exposure limit values for the protection of workers.

An analysis of economic, social and environmental impacts of the different policy options for each chemical agent was carried out[45]. The analysis was carried out on the basis of the IOM Study evaluation of the health, socio-economic and environmental aspects of the proposed amendments to the Directive. The comparison of the policy options and the choice of the preferred option were carried out on the basis of the following criteria: the scientific information (in particular SCOEL recommendations), 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 account of the cancer latency period.

For some carcinogens (e.g. trichloroethylene; mineral oils as used engine oils) a clear preferred value emerged. For others (e.g. epichlorohydrine and ethylene dibromide) identified costs/benefits of the baseline (no action) and setting an EU limit value were closely matched[46].

The measures agreed by the ACSH were retained as a policy choice in respect of all the chemical agents in this proposal.

As regards the impact on workers, this proposal should result in benefits in terms of preventing workers from getting avoidable work-related cancer, and thus preventing unnecessary suffering and illness. In addition, important health benefits are expected in relation to trichloroethylene and mineral oils as used engine oils. In the case of those two agents the retained option would also result, until 2069, in:

- Mineral oils as used engine oils: 880 saved lives, 90,000 less cancer cases and a monetised health benefit of €0.3-1.6 bn related to avoidance of health costs.
- Trichloroethylene: 390 saved lives and a monetised health benefit of €118-430m related to avoidance of health costs.

The introduction of the preferred option would therefore reduce cancer and decrease the economic burden derived by workers' exposure to hazardous substances.

As regards the impact on employers, it is important, from an economic point of view, to distinguish between costs that do or do not create incentives for improvements in health and

[45] See section 5 of the impact assessment for a detailed analysis of the impacts of the different policy options and the manner in which they compare.

[46] See section 5.9 of the impact assessment, summarizing the retained options on the basis of several criteria: stakeholder acceptance; size of the problem; legal clarity; health benefit and limited costs for business.

safety. The advantages for businesses of introducing EU wide limit values is that the proposal will help firms addressing costs that would, otherwise, negatively affect their business prospects in the long-term in the case of non-compliance.

For the majority of carcinogens, impacts are expected to be minimal as only small adjustments will need to be done in specific cases to ensure full compliance. The retained option will not impose any additional information obligations and will not lead to an increase in administrative burdens on enterprises.

As regards the impact on Member States/national authorities, given the substantial economic costs imposed on workers due to their exposure to hazardous substances, this proposal would also contribute to mitigating financial losses sustained by Member State's 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 will differ according to the present status of each chemical agent in each Member State, but should not be significant. Furthermore, establishment of limit values at EU level eliminates the need for national authorities to independently evaluate 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, mainly based on complaints filed during a given year and according to the inspection strategies defined by a given authority. It should also be added that the existence of a limit value, by bringing clarity regarding the acceptable 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 on the revision 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 that the proposal is appropriate.

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. The reason is that 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, limit values 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, due to differences in limit values at national level, there will be in some cases, depending on industry practice, 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 minimal as only small adjustments will be needed to ensure full compliance. Also this proposal will not impose any additional information obligations or lead to an increase in administrative burdens on firms and it is not likely to generate any significant environmental costs.

The most significant costs foreseen in the IOM study associated with the considered carcinogens relate to investment in closed systems for use of trichloroethylene. SMEs are most vulnerable to the capital cost required in moving to a closed system and may opt to close down or switch to an alternative substance or process (if technically feasible to do so). However, according to existing EU legislation (Article 5 (2) of Directive 2004/37/EC, REACH and the Solvent Emissions Directive) and to the voluntary charter promulgated by the European Chlorinated Solvent Association (ECSA), investment in closed systems is expected to occur already under the baseline in some sectors.

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 job quality and working conditions, 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 clear specific minimum requirements for worker protection in the form of EU-wide limit values for those agents.

It should not have a significant impact on the external competitiveness of EU firms as while non-EU countries have established a wide range of exposure values[47], the retained limit values are not in contrast with international practice.

- **Fundamental rights**

The objectives of the proposal are consistent with the fundamental rights as set out in the EU Charter of Fundamental Rights, in particular 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.

[47] See Table 3 in annex 7 in the impact assessment.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The monitoring of the number of occupational diseases and related occupational cancer cases using the available data sources is foreseen[48], as well as the monitoring of costs related to occupational cancer for economic operators (e.g. loss of productivity) and social security systems.

A compliance assessment will be carried out for the transposition. Given the data challenges explained earlier, it is suggested to made use of the next ex-post evaluation exercise (2012-2017) to define the baseline values (benchmark) that will allow assessing the effectiveness of the revision of the Directive. Evaluation of the practical implementation of the proposed amendments could possibly be based on the following period (2017-2022). This reflects the fact that due to the long latency periods to develop cancer (10 to 50 years), it will not be possible to measure the real impact of the revision before 15-20 years.

- **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(1)

Article 1(1) states that the Directive is amended through the addition in Annex I of a new point to include "work involving exposure to oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine".

The new entry is based on the definition of "mineral oils as used engine oils" given in the Opinion of the Scientific Committee on Occupational Exposure Limits ('SCOEL') No. 405 on Mineral Oils as Used Engine Oils, adopted on 9 June 2016. Mineral oils as used engine oils consist of blends of hydrocarbons (including paraffins, naphthenics, and complex/alkylated polyaromatics and lubricating additives).

[48] These include data that could be collected by Eurostat on occupational diseases if the results of the on-going feasibility study are positive, as well as on other 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.

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.

The entry concerning "polycyclic aromatic hydrocarbons mixtures containing benzo[*a*]pyrene which are carcinogens within the meaning of the Directive" is based on the final draft Recommendation from SCOEL No. 404 which addresses mixtures of polycyclic aromatic hydrocarbons containing benzo[*a*]pyrene as indicator compound due to the high potency of benzo[a]pyrene. There exists more than 100 single polycyclic aromatic hydrocarbons identified, and benzo[*a*]pyrene is one of them, but only a minor fraction of all polycyclic aromatic hydrocarbons (PAHs) has been studied toxicologically[49]. Benzo[a]pyrene as well as seven other polycyclic aromatic hydrocarbons subject to REACH restrictions[50] are classified as carcinogens, category 1B in Regulation (EC) No 1272/2008 (CLP), and are therefore under the scope of the Directive 2004/37/EC. In accordance with the CLP rules on classification of mixtures, polycyclic aromatic hydrocarbons mixtures meet the criteria for classification as carcinogenic category 1A or 1B, and therefore are carcinogens as defined in Directive 2004/37/EC, in the case where at least one ingredient meets the criteria for classification as a category 1A or 1B carcinogen and is present at or above the appropriate generic or specific concentration limits, as set forth in the CLP. It it therefore not necessary to include a dedicated entry in Annex I to the Directive for these mixtures.

As regards the relationship between the proposed entry concerning "*polycyclic aromatic hydrocarbons mixtures containing benzo[a]pyrene which are carcinogens within the meaning of the Directive*" in Part B of Annex III to the Directive, and the current entry 2 in Annex I to the Directive concerning "*work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch*", it must first be stated that by contrast to the latter entry, which concerns single polycyclic aromatic hydrocarbons present in certain by-products of coal[51], the proposed entry in Annex III concerns all polycyclic aromatic hydrocarbons mixtures which contain benzo[*a*]pyrene. It follows that the proposed entry in Part B of Annex III to the Directive covers the polycyclic aromatic hydrocarbons (PAHs) mixtures present in coal soot, coal tar or coal pitch containing benzo[*a*]pyrene which are carcinogens within the meaning of the Directive and that the skin notation associated with the proposed entry applies also to PAHs mixtures present in coal soot, coal tar or coal pitch containing benzo[*a*]pyrene which are carcinogens within the meaning of the Directive.

A 'skin notation' is assigned for each chemical agent where the SCOEL has assessed that dermal absorption could contribute substantially to the total body burden and consequently to

[49] See final draft Recommendation SCOEL/REC/404.

[50] Entry 50 of Annex XVII to REACH Regulation contain next to benzo[*a*]pyrene the following PAHs: benzo[e]pyrene (CAS No 192-97-2), benz[a]anthracene (CAS No 56-55-3), chrysene (CAS No 218-01-9), benzo[b]fluoranthene (CAS No 205-99-2), benzo[j]fluoranthene (CAS No 205-82-3), benzo[k]fluoranthene (CAS No 207-08-9), and dibenzo[a,h]anthracene (CAS No 53-70-3).

[51] See COM (95) 425 final.

concerns regarding possible health effects. A skin notation identifies the possibility of significant uptake through the skin. 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.

2017/0004 (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

(Text with EEA relevance)

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 Article 153(2) thereof,

Having regard to 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), and in particular Article 17(1) thereof[52],

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[53],

Having regard to the opinion of the Committee of the Regions[54],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2004/37/EC aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace and lays down minimum requirements to that effect including limit values, on the basis of the available scientific and technical data.

(2) For some carcinogens and mutagens it is necessary to consider other absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection.

(3) The Scientific Committee on Occupational Exposure Limits ('the Committee')[55] assists the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limit values for the protection of workers from chemical risks, to be set at Union level pursuant to Council Directive 98/24/EC[56] and

[52] OJ L 158, 30.4.2004, p. 50.

[53] OJ C , , p.

[54] OJ C , , p.

[55] Commission Decision 2014/113/EU 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).

[56] 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, 05.05.1998, p. 11).

Directive 2004/37/EC. Other sources of scientific information, adequately robust and in the public domain were also considered.

(4) In accordance with the recommendations of the Committee, where available, skin notations and/or 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 shorter reference periods, in general fifteen minutes time-weighted average (short-term exposure limit values), to take account of the effects arising from short-term exposure.

(5) There is sufficient evidence of the carcinogenicity of oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine. These used engine oils are process-generated and therefore they are not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[57]. The Committee identified the possibility of significant uptake through the skin for these oils, assessed that occupational exposure occurs through the dermal route and strongly recommended the establishment of a skin notation. It is therefore appropriate to include work involving exposure to oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine in Annex I to Directive 2004/37/EC and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(6) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures containing benzo[*a*]pyrene meet the criteria for classification as carcinogenic (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 and therefore are carcinogens as defined in Directive 2004/37/EC. The Committee identified the possibility of significant uptake through the skin for these mixtures. It is therefore appropriate to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(7) Trichloroethylene meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set limit values for trichloroethylene in relation to a reference period of eight hours (long-term limit value) and to a shorter reference period (15 minutes). The Committee identified for this carcinogen the possibility of significant uptake through the skin. It is therefore appropriate to establish long- and short-term exposure limit values for trichloroethylene in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake. In light of evolving scientific evidence, the limit values for this substance will be kept under particularly close review.

(8) 4,4'-Methylenedianiline (MDA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for 4,4'-Methylenedianiline. The Committee identified for this carcinogen the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value

[57] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1).

in Part A of Annex III for 4,4'-Methylenedianiline and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(9) Epichlorohydrine (1-chloro-2,3-epoxypropane) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. The Committee concluded that that is not possible to derive a health-based exposure limit value for this non-threshold carcinogen and has recommended avoiding occupational exposure. The Committee identified for epichlorohydrine the possibility of significant uptake through the skin. The Advisory Committee on Safety and Health at Work ('ACSH') has agreed on a practical limit value, on the basis of the available information, including scientific and technical data. It is therefore appropriate to establish a limit value for epichlorohydrine in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(10) Ethylene dibromide (1,2-dibromoethane, EDB) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. The Committee concluded that that is not possible to derive a health-based exposure limit value for this non-threshold carcinogen and has recommended avoiding occupational exposure. The Committee identified for ethylene dibromide the possibility of significant uptake through the skin. The Advisory Committee on Safety and Health at Work ('ACSH') has agreed on a practical limit value, on the basis of the available information, including scientific and technical data. It is therefore appropriate to establish a limit value for ethylene dibromide in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(11) Ethylene dichloride (1,2-dichloroethane, EDC) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen as defined in Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for ethylene dichloride. The Committee identified for ethylene dichloride the possibility of significant uptake through the skin. It is therefore appropriate to establish a limit value for ethylene dichloride in Part A of Annex III and to set out a skin notation in Part B of Annex III to Directive 2004/37/EC indicating the possibility of significant dermal uptake.

(12) In order to ensure internal coherence, it is appropriate to transfer the column "Notation" set out in Part A of Annex III to Directive 2004/37/EC and the notations set out in that column to Part B of Annex III to Directive 2004/37/EC.

(13) The Commission consulted the Advisory Committee on Safety and Health at Work, set up by Council Decision of 22 July 2003. It also carried out a two-stage consultation of the European social partners in accordance with Article 154 of the TFEU.

(14) This Directive respects the fundamental rights and principles enshrined in the Charter of Fundamental Rights of the European Union, in particular in Article 31(1) thereof.

(15) The limit values established in this Directive will be kept under review in the light of the implementation 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), 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[58] and of the opinions of the ECHA Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC), in particular to take account of the interaction between limit values established in Directive 2004/37/EC and dose-response relations, actual exposure information, and, where available, DNELs (Derived No Effect Levels) derived for hazardous chemicals in accordance with that Regulation.

(16) Since the objectives of this Directive, which are to improve living and working conditions and to protect the health of workers from the specific risks arising from exposure to carcinogens, cannot be sufficiently achieved by the Member States, but can be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5(3) of the Treaty on European Union. In accordance with the principle of proportionality, as set out in Article 5(4) of the TEU, this Directive does not go beyond what is necessary in order to achieve those objectives.

(17) Given that this Directive concerns the workers' health at their workplace, the deadline for transposition should be two years.

(18) Directive 2004/37/EC should therefore be amended accordingly.

(19) In accordance with the Joint Political Declaration of 28 September 2011 of Member States and the Commission on explanatory documents[59], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2004/37/EC is amended as follows:

(1). In Annex I the following point is added:

'Work involving exposure to oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine'.

(2). Annex III 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 not later than two years after the date of entry

[58] OJ L 396, 30.12.2006, p. 1.
[59] OJ C 369, 17.12.2011, p.14

into force of this Directive. 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 provisions of national law that 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*