ETUC calls for a more ambitious revision of the Carcinogens & Mutagens Directive (CMD)

Introduction

More than 100.000 people die every year in the European Union due to the lack of prevention against work related cancer[1].

A precise regulatory framework is the main driver of prevention against work related cancer since most of the costs are paid by the victims and the society. In 2012, the annual societal cost of work-related cancer in the EU was estimated to be at least in an order of magnitude of € 334 billion (242 – 444)[2].

For years, trade unions and different stakeholders have urged the Commission to make proposals for a better regulation on the prevention of work related cancer[3].

In May 2016, the Commission adopted a proposal (2016/0130 COD) focused on setting binding occupational exposure limits (BOELs) for 13 substances (2 revised BOELs and 11 new BOELs). In July 2017, the European Parliament and the Council reached an agreement on the first revision of the CMD which goes far beyond what the Commission originally proposed. Stricter BOELs have been adopted for Chromium VI compounds and hardwood dust. In addition, Member States will now have to organize lifelong health surveillance for workers exposed to carcinogens and the Commission has the obligation to explore the possibility of extending the scope of the directive to include substances toxic for reproduction by first quarter of 2019.

In January 2017, the Commission adopted another proposal to set BOELs for a second batch of 5 carcinogens (2017/0004 COD). We present here the principal trade union demands which are submitted to the Council of Ministers and to the European Parliament for this second Commission proposal. While welcoming it, ETUC nonetheless deplores its lack of ambition and calls on the co-legislators to improve it with the amendments detailed hereafter.

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[1] *Takala J, Eliminating occupationalted cancer in Europe and globally, 2015. Download on: http://www.etui.org/fr/content/download/21462/179550/file/WP+2015-10-Eliminating+occupational+cancer+Web+version.pdf*

[2] *National Institute for Public Health and the Environment, Work related cancer in the European Union. Size, impact and options for further prevention, 2016. Download on: http://nl.sitestat.com/rivm/rivm-nl/s?link.en.documents_and_publications.scientific.reports.2016.mei.work_related_cancer_in_the_european_union_size_impact_and_options_for_further_prevention_272940.download_pdf&ns_type=pdf&ns_url=http%3A%2F%2Fwww.rivm.nl%2Fdsresource%3Fobjectid=rivmp:315353&type=org&disposition=inline&ns_nc=1*

[3] *Musu T, Vogel L and Wriedt H, Cancer risks in the workplace: better regulation, stronger protection. Download on : http://www.etui.org/fr/content/download/23435/195303/file/WP-+2016+05-cancer+risks-web+version.pdf*

1. Introduction of Diesel Engine Exhaust Emissions (DEEE) in Annex I and Annex III

Summary of proposed amendments:
Diesel Engine Exhaust Emissions (DEEE) are among the process-generated carcinogens with the highest number of exposed workers in Europe. The inclusion of DEEE in the scope of the Carcinogens and Mutagens Directive (new entry in Annex I) and the establishment of a binding limit value of 50 µg/m³ measured as Elemental Carbon (new entry in Annex III) should significantly reduce the number of occupational lung cancers and other adverse health effects of DEEE in the EU-28.

Justification:
DEEE rank among the top 4 most prevalent process-generated carcinogens at the workplace[4] with up to 19 million workers potentially exposed in the EU. Inclusion of DEEE in Annex I will bring them in the scope of the Directive and the introduction of an OEL of 50 µg/m³ (measured as Elemental Carbon) in Annex III will reduce the number of future occupational lung cancer cases and other occupational adverse health effects due to DEEE exposure. This OEL has been recently adopted in Germany showing that it is achievable and technically feasible. It covers all types of Diesel engines (irrespective of whether the exhaust emissions are from old or new diesel engines).

What are the expected benefits?
The carcinogenicity of DEEE has been demonstrated extensively in the literature. According to the Commission impact assessment the absence of a legislative initiative would lead to 230,000 deaths over the coming 60 years. This order of magnitude is very much underestimated, given that it is based solely on deaths caused by lung cancer. When taking account of the other adverse health effects of diesel engine exhaust emissions (non-cancer respiratory diseases and cardiovascular diseases), the number of avoidable deaths is probably much higher.

More info:
Diesel engine exhaust emissions are complex and inhomogeneous mixtures of gases, aerosols and particles resulting from the combustion of diesel fuel. In 2012, the International Agency for Research on Cancer categorised diesel engine exhaust emissions as Class 1 carcinogens (proven human carcinogens)[5]. Occupational exposure to DEEE can occur in a wide variety of sectors including mining, railways, road transport, warehouse, etc. The number of workers exposed to DEEE in Europe is estimated to be between 8 and 19 million.

In January 2017, the European Commission decided not to include DEEE in its second proposal to amend the Carcinogens & Mutagens Directive (2017/0004 COD) despite a positive opinion from the tripartite Advisory Committee on Safety and Health[6]. The main reasons were the lack of clarity from a legal point of view on what exactly would be covered by a DEEE entry in Annex I and Annex III and the scientific uncertainty about the carcinogenicity of the emissions from new types of diesel engines. This debate is biased and irrelevant since, in practice, workers are exposed to fumes from both old and new diesel engines corresponding to widely varying emission standards (from Euro 1/Euro I to Euro 6/Euro VI emission standards). Moreover, the composition of diesel engine exhaust emissions is not solely dependent on emissions standards

[4] *: Identifying prevalent carcinogens at the workplace, RIVM Letter report, 2015-0107*
http://www.rivm.nl/bibliotheek/rapporten/2015-0107.pdf
[5] *https://monographs.iarc.fr/ENG/Monographs/vol105/mono105.pdf*
[6] *Doc 727/13 of the ACSH, adopted on 30/05/2013*

applied for their construction, but also varies because several other factors, including maintenance, filter systems, combustion temperature, etc. The goal of the Carcinogens Directive is not to define specific rules governing the design of diesel engines, their possible replacement or other measures determined by market rules but rather to protect workers from the risks related to carcinogens at work.

Specifically concerning the carcinogenicity of fumes from new types of diesel engines; the latest studies available suggest that the new diesel technologies used by manufacturers have changed the quality and quantity of diesel emissions with an expected reduction of the associated cancer risks.
However, the knowledge is too limited to conclude as to an absence of carcinogenicity of the exhaust emissions from all the new diesel technologies placed on the market[7,8].

The carcinogenic effects of exhaust emissions from diesel engines justify the adoption of all measures necessary to reduce exposure to these emissions including the establishment of an OEL like the one recently adopted in Germany to protect workers exposed to DEEE.

[7] *Diesel engine exhaust, the Nordic Group for Criteria Documentation of Health Risks from Chemicals and the Dutch Expert Committee on Occupational Safety, No 2016; 49(6)* *https://gupea.ub.gu.se/bitstream/2077/44340/1/gupea_2077_44340_1.pdf*

[8] *Anses Scientific and technical support note regarding on-road diesel vehicle emissions in France considering IARC Monograph Volume 105 on the carcinogenicity of engine exhaust emissions.(19 April 2017)* https://www.anses.fr/fr/system/files/AIR2014SA0156EN.pdf

Detailed proposed amendments:

Amendment 1
Proposal for a directive
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) There is sufficient evidence of the carcinogenicity of diesel engine exhaust emissions from old diesel engines. New diesel engine technology has changed the quality and quantity of diesel emissions and the associated cancer risks have been reduced but not eliminated. Due to the long transition time to switch from old to new diesel technology, a concomitant exposure to exhaust emissions from old and new diesel engines is expected to occur at work for the many years to come. Diesel engine exhaust emissions are process-generated and consequently they are not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council. **On the basis of available information, including scientific and technical data, a limit value for diesel engine exhaust emissions should be established. It is therefore appropriate to include work involving exposure to diesel engine exhaust emissions in Annex I and to establish a limit value for diesel engine exhaust emissions in Annex III to Directive 2004/37/EC. The entries in Annex I and Annex III should cover fumes from all types of diesel engine and are thus irrespective of whether the exhaust emissions are from old or new diesel engines.**

Amendment 2
Proposal for a directive
Article 1, point 1a (new)
Directive 2004/37/EC

Text proposed by the Commission	*Amendment*
	(1a). Work involving exposure to diesel engine exhaust emissions (irrespective of diesel engine types)

Justification:
Diesel engine exhaust emissions are complex and inhomogeneous mixtures of gases, aerosols and particles resulting from the combustion of diesel fuel. They are process-generated and consequently not subject to classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council. However, there is sufficient evidence of the carcinogenicity of diesel engine exhaust emissions (DEEE) from old diesel engines and the cancer risks of DEEE from new diesel engines have been reduced but not eliminated([a,b]). An entry for DEEE covering fumes from all types of diesel engine is therefore needed in Annex I of CMD to bring them in the scope of Directive 2004/37(EC).

([a]): Diesel engine exhaust, the Nordic Group for Criteria Documentation of Health Risks from Chemicals and the Dutch Expert Committee on Occupational Safety, No 2016; 49(6)
https://gupea.ub.gu.se/bitstream/2077/44340/1/gupea_2077_44340_1.pdf

([b]) *Anses Scientific and technical support note regarding on-road diesel vehicle emissions in France considering IARC Monograph Volume 105 on the carcinogenicity of engine exhaust emissions.(19 April 2017)*
https://www.anses.fr/fr/system/files/AIR2014SA0156EN.pdf

Amendment 3
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 3 – **new line**

Text proposed by the Commission	Amendment
	Diesel engine exhaust emissions (irrespective of diesel engine types)

Amendment 4
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 – sub-column 8 hours – sub-column mg/m³– **new line**

Text proposed by the Commission	Amendment
	0.05([8])

[8] measured as elemental carbon

Justification:

The transition from old to new technology diesel engine is expected to take a long time and workers will be exposed to both emissions from old and new diesel engines in the next 15-20 years. DEEE from both old and new diesel engines are characterised by the presence of carcinogenic compounds([a]). A limit value for DEEE covering all types of diesel engine is therefore needed in Annex III. Introducing a binding OEL of 0,05 mg/m³ measured on Elemental Carbon is likely to have a positive health impact on the 8-19 million of EU workers exposed to DEEE at work. This OEL has been recently adopted in Germany showing that it is achievable and technically feasible.

([a]): *Anses Scientific and technical support note regarding on-road diesel vehicle emissions in France considering IARC Monograph Volume 105 on the carcinogenicity of engine exhaust emissions.(19 April 2017)*
https://www.anses.fr/fr/system/files/AIR2014SA0156EN.pdf

Amendment 5
Proposal for a directive
Article 18a, Evaluation
Directive 2004/37/EC as agreed by the Parliament and the Council on 11 July 2017

Text proposed by the Commission	*Amendment*
The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also evaluate the need to modify the limit value for respirable crystalline silica dust. The Commission shall propose, where appropriate, necessary amendments and modifications relating to such substances.	The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also evaluate the need to modify the limit value**s** for respirable crystalline silica dust **and diesel engine exhaust emissions.** The Commission shall propose, where appropriate, necessary amendments and modifications relating to such substances.
No later than in the first quarter of 2019, the Commission shall, taking into account latest developments in scientific knowledge, assess the option of amending the scope of this Directive to include reprotoxic substances. On this basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.	No later than in the first quarter of 2019, the Commission shall, taking into account latest developments in scientific knowledge, assess the option of amending the scope of this Directive to include reprotoxic substances. On this basis, the Commission shall present, if appropriate, and after consulting management and labour, a legislative proposal.

Justification:

According to the SCOEL opinion on Diesel Engine Exhaust[9]: "although toxicological data supports a threshold (possibly at 0.02 mg DEP/m³ or below, corresponding 0.015 mg EC/m³), epidemiological data suggests significant cancer risks already at and below these exposure levels". There is therefore a need to evaluate whether the OEL for diesel engine exhaust

[9] *SCOEL/OPIN/403 Diesel Engine Exhaust page 10.*

emissions (0.05 EC mg/m³) should be reduced to 0.015mg EC/m³ in order to take into account epidemiological data as mentioned by the SCOEL:

2. Introduction of Polycyclic Aromatic Hydrocarbons (PAHs) mixtures in Annex I and in Annex III

Summary of proposed amendments:
Polycyclic Aromatic Hydrocarbons (PAHs) mixtures are among the process-generated carcinogens with the highest number of exposed workers in Europe. A better definition of PAHs mixtures in Annex I and the establishment of a binding limit value of 0,00007 mg/m³ with benzo[a]pyrene as indicator (new entry in Annex III, part A with 3 years transition period 0,0007 mg/m³) on top of the skin notation (in Annex III, part B) proposed by the Commission should significantly reduce the number of occupational lung cancers and other adverse health effects of PAHs mixtures in the EU-28.

Justification:
The current Annex I entry covers major sources of occupational exposure to PAHs but is unclear on which other occupational exposure situations exist during which workers are exposed to these substances and their mixtures. Benzo[a]pyrene is commonly used as a quantitative indicator compound within complex mixtures of PAHs. Since the national OELs for benzo[a]pyrene as a marker of total PAH concentration differ from one country to another, there is a need to harmonize workers' protection in the EU by introducing an OEL in Annex III, part A of CMD. The OEL of 0.00007 mg/m³ already enforced in Germany should serve as a best practice example at EU level.

What are the expected benefits?
According to the Commission Impact assessment 7 million workers in the EU were exposed to levels of benzo[a]pyrene up to 0.001 mg/m³ in 2006 and the base line scenario (no OEL introduced at EU level) estimates the health cost range in the period 2010-2069 to amount between €6,2 and 194 billion mostly due to previous exposure. The OEL adopted at EU level should help avoid future cancer cases and reduce these health costs significantly.

More info:
Polycyclic aromatic hydrocarbons (PAHs) are a large class of organic compounds with more than 100 single PAHs identified. They are ubiquitously formed during burning and pyrolysis of organic materials (i.e. processing and use of coal-derived products, automobile and truck emissions, burning of wood, etc.). They are found in air, water and food. The most extensive studied individual PAH is benzo[a]pyrene which is one of the strongest genotoxic carcinogens (classified as human carcinogen -group 1- by IARC) and which significantly contributes to the carcinogenic potency of PAH-rich mixtures. SCOEL consider it as a quantitative indicator for general airborne PAH exposure. Benzo[a]pyrene as well as seven other PAHs are classified as Carcinogen 1B in the EU CLP Regulation. PAHs have been linked to lung, skin, bladder, liver and stomach cancer in well-established animal studies. Exposure to PAHs has also been linked with cardiovascular disease and poor foetal development. The major source of occupational exposure to PAHs are the production and use of coal tar and coal-tar derived products. Workers in industries or trades using or producing coal or coal products are at highest risk for PAH exposure. Those workers include, but are not limited to aluminum workers, asphalt workers, carbon black workers, chimney sweeps, coal-gas workers, coke oven workers, fishermen (coal tar on nets), graphite electrode workers, mechanics (auto and diesel engine), road (pavement) workers, roofers, steel foundry workers, tire and rubber manufacturing workers, etc. Safe health-based OEL cannot be derived for PAHs and every level of exposure carries risks of contracting cancer. According to SCOEL, a mean airborne 8h TWA PAH exposure over 40

working years in the order of 0.0006 mg/m³ benzo[a]pyrene would lead to an excess cancer mortality rate of 4 X 10^{-3} (4 deaths over 1000 exposed workers).

Detailed proposed amendments:

Amendment 1
Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(6) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, particularly those 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. Exposure to such mixtures may occur during work involving burning processes, such as from combustion engine exhaust, and high temperature combustion processes, among others. ~~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.	(6) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, particularly those 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. Exposure to such mixtures may occur during work involving burning processes, such as from combustion engine exhaust, and high temperature combustion processes, among others. **The existing entry 2 in Annex I should therefore be extended to also cover other occupational exposure situations during which workers are exposed to these substances and their mixtures. In addition, on the basis of available information, including scientific and technical data, it is appropriate to establish a limit value for PAHs mixtures with benzo[*a*]pyrene as indicator in part A 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.

Amendment 2
Proposal for a directive
Article 1, point 1b (new)
Directive 2004/37/EC

Text proposed by the Commission	*Amendment*
	(1b). Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch and work involving exposure to carcinogenic polycyclic aromatic hydrocarbons, in particular in any burning process, such as

	from combustion engine exhaust, and high temperature combustion processes, among others.

Justification:
The existing entry 2 in Annex I should be extended to also cover other occupational exposure situations during which workers are exposed to these substances and their mixtures.

Amendment 3
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 3 – **new line**

Text proposed by the Commission	Amendment
	Polycyclic aromatic hydrocarbons mixtures containing benzo[*a*]pyrene which are carcinogens within the meaning of the Directive

Amendment 4
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 – sub-column 8 hours – sub-column mg/m³– **new line**

Text proposed by the Commission	Amendment
	0.00007([9])

[9] benzo[*a*]pyrene as a marker of total PAH concentration

Amendment 4
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 5 – Transitional measures– **new line**

Text proposed by the Commission	Amendment
	0.0007 mg/m³ ([9]) until 3 years after entry into force

Justification:
A transition period of 3 years at 0.0007 mg/m³ is needed to allow companies across the different Member States to meet the German BOEL at 0.00007 mg/m³ which is currently the best practice in the EU.

3. Stricter BOELs for Trichloroethylene

Summary of proposed Amendments:

Annex III (A) should read:

CAS No	*EC No*	*Name of agent*	*Limit values*						*Transitional measures*
			8 hours			*Short-term*			
			mg/m³	*ppm*	*f/ml*	*mg/m³*	*ppm*	*f/ml*	
79-01-6	*201-167-4*	*Trichloroethylene*	~~*54,7*~~ ***3,3***	~~*10*~~ **0,6**		~~*164,1*~~ ***13,2***	~~*30*~~ ***1,8***		-

Justification:

The OELs (8 hours and short-term) proposed by the Commission are based on the SCOEL recommendation from 2009 and the EU Advisory Committee on Health & Safety opinion from 2012. Trichloroethylene has since been subject to REACH authorisation requirements and new data are therefore available. Up to 22 700 workers are exposed (directly or indirectly) to trichloroethylene in the EU-28 for uses in the scope of REACH authorisation and the vast majority of these workers are reported to be exposed at levels below 3 mg/m³ (8 hrs) [10]. Moreover, two EU countries (AT & DE) provide a higher level of protection compared to the BOEL proposed by the Commission with national limit values of 3,3 mg/m³ (8 hrs) and 13.2 mg/m³ (short-term). Both the data from REACH and the existing stricter limit values at National level demonstrate that more protective BOELs are achievable and technically feasible for trichloroethylene.

What are the expected benefits?

In contrast to the conclusions from the Commission's impact assessment[11] (mainly based on an IOM report from 2011), the latest available data from 2017 suggest that the costs and benefits of a limit value at 54.7 mg/m³ (10 ppm) are expected to be minimal[4]. As the baseline scenario (no EU OEL introduced for trichloroethylene) foresees 3 290 attributable deaths for the period 2010-69, introducing an OEL at 3,3 mg/m³ (0,6 ppm) should bring significant health benefits due to a reduction in exposure and a decrease in these attributable deaths.

More info:

Trichloroethylene is classified as a group 2A carcinogen by IARC and as a category 1B carcinogen under the EU CLP regulation. Exposure to trichloroethylene is associated with increased risks of kidney, liver and biliary cancers and non-Hodgkin's Lymphoma. The ECHA Risk Assessment Committee considers the substance to be 'non-threshold'.[12]

Trichloroethylene is a volatile organic compound that has been used in the production of chemicals and chemical products, the manufacturing sector, the textile industry and the mining sector. Many uses have ceased as a result of REACH authorisation. A total of 19 applications for authorisation have been submitted by the Latest Application Date of 21/10/2014 and uses other than the ones applied for are no longer possible[13]. Exposure levels are understood to have started declining even prior to REACH both as a result of the implementation of the Solvents Emission Directive as well as a voluntary industry commitment for the safe use of

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[10] Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Dir 2004/37/EC. Final Report, RPA, January 2017. Ref Ares(2017)277357 -18/01/2017.

[11] Impact Assessment SWD (2017) 7 final (10-01-2017) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017SC0007&qid=1494252654307&from=EN

[12] Every level of exposure, however low, brings with it risks of contracting cancer

[13] With the exception of manufacture and the use as an intermediate which are exempted from authorisation. However manufacture and intermediate uses generally take place in closed systems with no likelihood of exposure or with occasional controlled exposure.

trichloroethylene in metal cleaning and degreasing through the use of closed systems and substitution.

Detailed proposed amendments:

Amendment 1
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 – sub-column 8 hours – sub-column mg/m³– line 1

Text proposed by the Commission	Amendment
54,7	**3.3**

Amendment 2
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 – sub-column 8 hours – sub-column ppm – line 1

Text proposed by the Commission	Amendment
10	**0.6**

Amendment 3
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 –sub-column Short-term – sub-column mg/m³ – line 1

Text proposed by the Commission	Amendment
164.1	**13.2**

Amendment 4
Proposal for a directive Annex Directive 2004/37/EC
Annex III –part A –column 4 –sub - column Short-term – sub-column ppm – line 1

Text proposed by the Commission	Amendment
30	**1.8**

4. Stricter BOEL for Ethylene dichloride (EDC)

Summary of proposed Amendments:
Annex III (A) should read:

CAS No	*EC No*	*Name of agent*	*Limit values*						*Transitional measures*
			8 hours			*Short-term*			
			mg/m³	*ppm*	*f/ml*	*mg/m³*	*ppm*	*f/ml*	
107-06-2	203-458-1	*Ethylene dichloride*	~~*8,2*~~ ***4,0***	~~*2*~~ **1**	**–**	-	-	-	-

Justification:
Several EU countries have adopted an OEL for EDC of 4 mg/m³ (BG, DK, EE, FI, SE) and there is a need to follow the best practice from different Member States in setting BOELs for carcinogens. It also demonstrates that a more protective BOEL is achievable and technically feasible.

What are the expected benefits?
A stricter BOEL is more effective in reducing exposure and therefore the number of possible cancer cases and deaths. The main use of EDC (more than 99 % of the total volume in the EU) is as intermediate in the manufacture of vinyl chloride monomer (VCM). REACH data suggest exposure concentrations in sites producing EDC and VCM are at present around 4 mg/m³ or less. Adopting a BOEL of 4 mg/m³ would be coherent with the state of the art and would avoid industry relaxing its efforts to control EDC exposure.

More info:
EDC (also known as 1,2-dichloroethane) is classified as non-threshold carcinogen (IARC Group 2B and CLP Category 1B). It is estimated that around 3000 workers are exposed to EDC in the EU-28. EDC is also subject to REACH authorisation requirements and 12 applications for authorisation have been submitted by the Latest Application Date of 22/05/2016. About 0.2 % of the total tonnage of EDC is estimated to be used within the scope of authorisation (i.e. solvent in different applications whereas manufacture and use as intermediate are out of scope). For all uses applied for the exposure to EDC is reported to be below 2 mg/m³.

Detailed proposed amendments:
Amendment 1
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 – sub-column 8 hours – sub-column mg/m³– line 5

Text proposed by the Commission	Amendment
8,2	**4,0**

Amendment 2
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 – sub-column 8 hours – sub-column ppm – line 5

Text proposed by the Commission	Amendment
2	**1**

5. Inclusion of Formaldehyde in Annex III

Summary of proposed amendments:

Annex III (A) should read **(new)**:

CAS No	*EC No*	*Name of agent*	*Limit values*						*Transitional measures*
			8 hours			*Short-term*			
			mg/m³	*ppm*	*f/ml*	*mg/m³*	*ppm*	*f/ml*	
50-00-0	***200-001-8***	***Formaldehyde***	***0,369***	**0,3**		***0,738***	***0,6***		-

Justification:

Formaldehyde ranks among the 10 most prevalent carcinogenic substances at the workplace. In 2016, The Scientific Committee on Occupational Exposure Limits (SCOEL) published its revised recommendation and concluded that formaldehyde is a genotoxic carcinogen with a threshold mode-of action. SCOEL also confirmed a safe exposure limit at 0.3ppm (8h- long-term) and 0,6 ppm (short-term). In addition, the Advisory Committee of Safety and Health at work representing the Trade Unions, Employers and National Authorities issued an opinion calling for the inclusion of formaldehyde on the Annex III of CMD as soon as possible. Given the special nature of formaldehyde (carcinogen with threshold), the scientific consensus on the safe exposure level and the large consensus among social partners on the value, formaldehyde should be added to the Annex III.

What are the expected benefits?

Currently, there is no EU harmonised OELs for formaldehyde. National OELs are in place in most of the EU countries (varying from 0.3 to 2 ppm – long term). A binding OEL would support a better level playing field and provide legal certainty to operators. According to the recent Risk Management Option Analysis performed on formaldehyde, several industrial sectors have been identified where long-term exposure to formaldehyde is higher than 0,3 ppm (building, chemicals & plastic industry, wood, paper, textile and health care sectors). It is expected that the establishment of the proposed binding OELs (long-term and short-term) in the Carcinogens & Mutagens Directive will help avoiding a considerable number of future occupational cancer deaths in these industrial sectors.

More info:

Formaldehyde is a high-production volume chemical (over 3.6 million t/y in the EU-28) with a wide array of uses. It is used as a chemical intermediate in the manufacture of industrial chemicals, in the production of various types of resin which have wide uses as adhesives and binders in wood-production, pulp and paper, in the production of plastics and coatings and in textile finishing. It is also used as a disinfectant and preservative in many applications (embalmers, pathologists, etc.). Formaldehyde is classified as human carcinogen (group 1) by IARC and Carcinogen 1B and skin sensitiser under the EU CLP Regulation. According to IARC, there is sufficient evidence in humans that formaldehyde causes nasopharyngeal cancer, sinonasal cancer and leukaemia. It is estimated that 1.8 million workers are potentially exposed to formaldehyde in the EU-28. The European Commission indicated its intention to establish binding OELs for formaldehyde in the 3rd batch of carcinogens due in 2018 after a proper impact assessment is available. However, given the large consensus between employers/industry and trade unions, the social partners propose to avoid red-tape and already include formaldehyde in the 2nd legislative amendment of the Carcinogens & Mutagens Directive.

Detailed proposed amendments:

Amendment 1 **(new)**
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 1 – CAS No– **new line**

Text proposed by the Commission	Amendment
	50-00-0

Amendment 2 **(new)**
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 2– EC No **- new line**

Text proposed by the Commission	Amendment
	200-001-8

Amendment 3 **(new)**
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 3– Name of Agent **- new line**

Text proposed by the Commission	Amendment
	Formaldehyde

Amendment 4 **(new)**
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 –sub-column 8 hours – sub-column mg/m³ – **new line**

Text proposed by the Commission	Amendment
	0,369

Amendment 5 **(new)**
Proposal for a directive Annex Directive 2004/37/EC
Annex III – part A – column 4 – sub-column 8 hours – sub-column ppm – **new line**

Text proposed by the Commission	Amendment
	0,3

Amendment 6 **(new)**
Proposal for a directive Annex Directive 2004/37/EC
Annex III –part A –column 4 –sub - column Short-term – sub-column mg/m³ – **new line**

Text proposed by the Commission	Amendment
	0,738

Amendment 7 **(new)**
Proposal for a directive Annex Directive 2004/37/EC
Annex III –part A –column 4 –sub - column Short-term – sub-column ppm – **new line**

Text proposed by the Commission	Amendment
	0,6

6. Inclusion of hazardous drugs including cytotoxic effects in the annex I of the CMD

Summary of proposed Amendments:
Inclusion of work involving exposure to carcinogenic or mutagenic substances in the treatment of patients with hazardous drugs.

Justification:
Every year more than 12.7 million healthcare workers in Europe, including 7.3 million nurses, are exposed to carcinogenic, mutagenic and reprotoxic hazardous drugs. According to EU-OSHA, these drugs represent the most dangerous chemical risk factors in healthcare and some of the most hazardous chemicals ever developed. Studies show that hospital workers who handle cytotoxic drugs are three times more likely to develop malignancy. It is estimated that in Europe each year occupational exposure to hazardous drugs produces 2,220 new cases of leukemia alone which results in 1,467 additional deaths of healthcare workers each year.

Studies show that nurses exposed to cytotoxic drugs are twice as likely to miscarry and among healthcare workers exposed to hazardous drugs in Europe it is estimated that occupational exposure produces 17,185 incremental miscarriages each year. Occupational exposure also produces 10,108 more malformations in children each year in Europe. Increased genetic damage has been demonstrated in nurses particularly in day hospital nurses, the group handling the highest amount of drugs during the administration process.

What are the expected benefits?
The Carcinogens and Mutagens Directive (2004/37/EC) does not currently acknowledge the dangers of hazardous drugs in healthcare or detail how they should be prevented. The Directive should recognize the problem of occupational exposure to hazardous drugs in healthcare. By improving preventative measures, the Directive would increase the sustainability of the health care system and guarantee to its staff a better health protection.

More info:
Hazardous drugs (also referred to as cytotoxic, cytostatic or antineoplastic drugs) describe a group of medicines designed to destroy cells that grow in a rapid and uncontrolled manner, preventing their replication or growth. Worldwide, these medicines are increasingly being used in a variety of healthcare settings, prominently in the treatment of cancer. They also play an important role in haematology and rheumatology and are used to treat non-cancerous diseases such as multiple sclerosis, psoriasis and systemic lupus erythematosus, leading to a growing use of these drugs.

The cytotoxic drugs available for current use are generally non-selective, meaning that they do not differentiate between malignant cells and normal healthy tissue and are therefore likely to damage normal (non-tumour) cells, resulting in adverse health effects.

Sold in powder or as a concentrated solution, a form where a drug is more stable, cytotoxic drugs require individual manipulation for each patient prior to being administered as infusions or bolus injections. This may lead to errors, spillages, needle stick injuries and (spread of) contamination, which pose clear health risks to healthcare workers. Moreover, cytotoxic drugs may evaporate and form a gas during normal handling which may result in inhalation of the drugs.

Surveys, conducted primarily with nurses, have associated workplace exposures to cytotoxic drugs with acute health effects and/or chronic effects. Indeed, increased genetic damage has been demonstrated in nurses, particularly in day hospital nurses, the group handling the highest amount of drugs during the administration process.

Importantly, the effects of exposure may be subclinical and not be evident for years or generations of continuous exposure. For example, as cancer often takes decades to emerge, a case of leukaemia diagnosed in a nurse or in a pharmacist today might be the product of workplace exposures in the 1970s or the 1980s. Unfortunately, in many instances, the connection between work and disease is never made.

While patients receive concentrated doses of a limited number of cytotoxic drugs for a defined period of time, healthcare workers may be exposed to small doses of a broad range of with cytotoxic drugs over decades, with some workers being exposed every workday, year after year.

More info on: http://www.europeanbiosafetynetwork.eu/

Detailed proposed amendments:

Amendment 1 **(new)**
Proposal for a directive Annex I to Directive 2004/37/EC
Annex I – **new line**

Text proposed by the Commission	Amendment
	"Work involving exposure to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs or materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs".