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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Delegations will find enclosed the four column table on the above-mentioned proposal

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.

2020/0262(COD)

Including compromise proposals for consideration at SQWP on 29.06.2021

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Formula					
1	2020/0262 (COD)	2020/0262 (COD)	2020/0262 (COD)	2020/0262 (COD)	
Proposal Title					
2	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.	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.	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-	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-	
Formula					
3	THE EUROPEAN PARLIAMENT AND THE	THE EUROPEAN PARLIAMENT AND THE	THE EUROPEAN PARLIAMENT AND THE	THE EUROPEAN PARLIAMENT AND THE	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	COUNCIL OF THE EUROPEAN UNION,	COUNCIL OF THE EUROPEAN UNION,	COUNCIL OF THE EUROPEAN UNION,	COUNCIL OF THE EUROPEAN UNION,	
Citation 1					
4	Having regard to the Treaty on the Functioning of the European Union, and in particular point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) thereof,	
Citation 2					
5	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	
Citation 3					
6	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	
Citation 3a					
6a			having regard to the Charter of Fundamental		

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			Rights of the European Union, and in particular Article 2 (the right to life) and Article 31(the right to fair and just working conditions),		
Citation 4					
7	Having regard to the opinion of the European Economic and Social Committee ¹ , 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee ¹ , 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee ¹ , 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee ¹ , 1. OJ C , , p. .	
Citation 5					
8	Having regard to the opinion of the Committee of the Regions ¹ , 1. OJ C , , p. .	Having regard to the opinion of the Committee of the Regions ¹ , 1. OJ C , , p. .	Having regard to the opinion of the Committee of the Regions ¹ , 1. OJ C , , p. .	Having regard to the opinion of the Committee of the Regions ¹ , 1. OJ C , , p. .	
Citation 6					
9	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Formula					
10	Whereas:	Whereas:	Whereas:	Whereas:	
Recital 1					
11	(1) Directive 2004/37/EC of the European Parliament and the Council ¹ aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.	(1) Directive 2004/37/EC of the European Parliament and the Council ¹ aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.	(1) Directive 2004/37/EC of the European Parliament and the Council ¹ aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A ~~consistent~~ high level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.	(1) Directive 2004/37/EC of the European Parliament and the Council ¹ aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	1. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).	1. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).	1. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).	1. Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).	
Recital 1a					
11a			(1a) This Directive clearly shows the added value of the Union and the need to adopt legislation at Union level. In addition to setting similar minimum level of protection across the Union, this Directive also improves clarity and enforcement, and contributes to a better level playing field for the economic actors in the sectors using the substances covered.		<u>Compromise proposal:</u> By setting minimum requirements for workers' protection across the Union, this Directive improves clarity (..) and contributes to a more better level playing field for the economic actors in the sectors that use ~~using~~ the substances falling within its scope covered , thereby demonstrating the added value importance of a Union action in this field. Preliminary agreed.

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Recital 1b					
11b			(1b) In the workplace, workers and other persons are often exposed to a cocktail of substances, which can increase health risks, cause adverse effects on their reproductive systems and cause impaired fertility or infertility, and have a negative impact on foetal development and lactation. Substances which are toxic to reproduction are of very high concern and the organisation of workplace prevention should apply the same approach to reprotoxic substances as for carcinogens and mutagens. As not all reprotoxic substances are threshold substances, it is of the utmost importance to enlarge the scope of Directive 2004/37/EC to reprotoxic substances in		Reprotoxic

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			order to bring it in line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council¹. This is necessary to better protect workers and their children and to ensure the safe participation of all workers in the workplace, in particular female workers who are pregnant or breastfeeding. In Regulation (EC) No 1907/2006, half of the 211 substances identified as substances of very high concern are reprotoxic substances. As is the case in some Member States, the organisation of workplace prevention should therefore apply the same approach to carcinogens, mutagens and reprotoxic substances, thus ensuring legal coherence and a level playing field across Member States. ¹. Regulation (EC) No		

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			1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).		
Recital 1c					
11c			(1c) A high level of human health protection should be ensured in the definition and implementation of all Union policies and		Rows 11c+17: EP could accept the Council amendment on reciprocal basis with Council acceptance for row 11c.

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			activities.		
Recital 2					
12	(2) Principle 10 of the European Pillar of Social Rights¹, jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens and mutagens at the workplace. 1. European Pillar of Social Rights, November 2017, available at : https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf	(2) Principle 10 of the European Pillar of Social Rights¹, jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens and mutagens at the workplace. 1. European Pillar of Social Rights, November 2017, available at : https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf	(2) Principle 10 of the European Pillar of Social Rights¹, jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens, mutagens and reprotoxic substances and mutagens at the workplace, irrespective of the arrangements for and duration of the employment or the exposure. 1. European Pillar of Social Rights, November 2017, available at : https://ec.europa.eu/commission/sites/beta-political/files/social-	(2) Principle 10 of the European Pillar of Social Rights¹, jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens and mutagens at the workplace. ~~1. European Pillar of Social Rights, November 2017, available at : https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf~~	Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			summit-european-pillar-social-rights-booklet_en.pdf		
Recital 2a					
12a			(2a) Europe's Beating Cancer Plan, set out in the Commission communication of 3 February 2021, aims to reduce the cancer burden for patients, their families and health systems. Cancer is the primary cause of work-related death in the Union: 52 %¹ of annual occupational deaths are currently attributed to work-related cancers. Exposure at work accounts for 5,3 to 8,4 %² cases of cancer and is responsible for approximately 120 000³ cancers diagnosed and more than 100 000⁴ deaths every year. Therefore, following the amendments to Annex III to Directive 2004/37/EC, as set out in this Directive, further limit values for		Reprotoxic

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			additional substances or group of substances and processes should be introduced by end of 2024. Between 50 and 70 substances or group of substances have been identified by different agencies, stakeholders, and the World Health Organization in priority lists of workplace carcinogens, mutagens and reprotoxic substances for which binding limit values are needed. The Commission should, no later than the end of 2021, put forward an action plan to achieve occupational exposure limits for at least 25 additional substances or group of substances or process generated substances. The additional substances or group of substances referred to in Annex III to Directive 2004/37/EC should include but not be limited to substances and processes such as welding		

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			fumes, benzo[a]pyrene/Poly Aromatic Hydrocarbons (PAHs), α-Chlorotoluene (Benzyl Chloride), Nitrosamines, soot, Silicone carbide fibers, 1,2-Dichloropropane, 1,2-Dihydroxybenzene (pyrocatechol), 2-Chloro-1,3-butadiene (Chloroprene), 2,3-Epoxypropyl methacrylate (glycidyl methacrylate), Anthraquinone , N-(Hydroxymethyl) acrylamide (NMA), 1,2-Dichloropropane, 1,2,3-Trichloropropane, Butanone oxime, Ethylene imine (Aziridine), 1-4dioxane, isoprene. Reprotoxic substances should include lead and lead compounds, Bisphenol-A, Carbon Monoxide, Mercury and divalent inorganic mercury compounds, N-methyl-2-pyrrolidone, N,N-Dimethylacetamide, Nitrobenzene, N,N		

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			Dimethylformamide, 2-Methoxy ethanol, 2-Methoxyethyl acetate, 2-Ethoxyethanol, 2-Ethoxyethyl acetate, di(2-ethylhexyl)phthalate, benzyl butyl phthalate and dibutyl phthalate. 1. https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1691 2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4551060/ 3. https://osha.europa.eu/en/themes/work-related-diseases/work-related-cancer 4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4551060/		
Recital 3					
13	(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values	(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values	(3) Binding occupational exposure limit values are important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values	(3) Binding occupational exposure limit values are an important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded.	Reprotoxic <u>Preliminary agreement to use</u> « up-to-date » when referring to scientific and technical data.

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	and other directly related provisions should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible.	and other directly related provisions should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible.	and other directly related provisions should be established for all those carcinogens, mutagens and reprotoxic substances ~~or mutagens~~ for which the available information, including updated scientific and technical data, make this possible.	Limit values and other directly related provisions should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible.	
Recital 3a					
13a				(3a) For mutagens and most of the carcinogens, it is not scientifically possible to identify levels below which exposure would not lead to adverse effects. While setting the limit values at the workplace in relation to carcinogens and mutagens pursuant to this Directive does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of	EP agrees preliminary.

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				risks arising from such exposure in the stepwise and goal-setting approach adopted in Directive 2004/37/EC. For some carcinogens, it is scientifically possible to identify levels below which exposure will not lead to adverse effects.	
Recital 4					
14	(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the	(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the	(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens, mutagens and reprotoxic substances ~~and mutagens~~ at the workplace, the prevention or reduction of workers' exposure to carcinogens, mutagens or reprotoxic substances ~~or mutagens~~ and the measures which should be implemented to that effect. Those measures	(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the	Reprotoxic

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	carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.	carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.	should include, as far as it is technically possible, the replacement of the carcinogen, mutagen and reprotoxic substance or ~~mutagen~~ by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.	carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.	
Recital 4a					
14a			(4a) There is a need for in-depth knowledge on the effect of the substances handled by workers in the healthcare sector. The training that the employer is required to provide pursuant to Article 11 of Directive 2004/37/EC should not only be provided periodically to workers in the healthcare sector but should be provided systematically to all healthcare workers who		HMP

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			are exposed to cytotoxic substances or mutagens.		
Recital 4b					
14b			(4b) In addition to the requirements set out in Article 5(5) of Directive 2004/37, employers in the health and social care sectors should prevent the exposure to carcinogens, mutagens and reprotoxic substances of workers, patients and their family members who are pregnant, breast feeding or trying to conceive.		Reprotoxic HMP
Recital 4c					
14c			(4c) Tackling exposures to dangerous substances at the workplace is particularly relevant for the purpose of fostering prevention and address health inequalities, as some categories of workers among the most vulnerable can be		Reprotoxic HMP

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			overexposed or more vulnerable to different types of substances. Women, for example, are over-represented among oncology nurses , who are potentially exposed to hazardous medicinal products. In sectors in which workers are exposed to carcinogens, mutagens or reprotoxic substances, gender mainstreaming should be an integral part of the development of occupational safety and health policies and prevention strategies. Member States' authorities should, in consultation with the social partners, take steps to mainstream gender equality and considerations to workers with disabilities and LGBTQI+ in the implementation of Articles 7, 8 and 10 of Directive 2004/37/EC, in particular with regard to sanitary facilities, work		

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			equipment and personal protective equipment.		
Recital 4d					
14d			(4d) Some workers, such as mobile workers, can additionally face difficulties in accessing healthcare services. Moreover, sectors such as the steel and chemicals industry as well as the cleaning sector in health services rely on posted, mobile and migrant workers. Member States' authorities should ensure, in particular, that the measures on the prevention and reduction of exposure measures for workers set out in Article 5, as well as the information and training requirement provided for in Articles 11 and 12 of Directive 2004/37/EC take into consideration the vulnerable situation of posted, mobile and migrant workers.		

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Recital 4e					
14e			(4e) Commission Recommendation 2003/670/EC¹ recommends that Member States introduce into their national laws, regulations or administrative provisions concerning scientifically recognised occupational diseases liable for compensation and subject to preventive measures. Member States should ensure that every worker has the right to compensation in respect of occupational diseases if he or she is suffering from an ailment which can be proved to be occupational in origin and nature. 1. Commission Recommendation 2003/670/EC of 19 September 2003 concerning the European schedule of occupational diseases (OJ L 238, 25.9.2003, p. 28).		To be considered by the Council <u>EP compromise proposal recital 4e (row 14e):</u> Commission Recommendation 2003/670/EC¹ recommends that Member States introduce into their national laws, regulations or administrative provisions concerning scientifically recognised occupational diseases liable for compensation and subject to preventive measures and to take steps to introduce the Member States should ensure that every worker has the right to workers' compensation in respect of occupational diseases if they are suffering from an ailment which can be proved to be occupational in origin and nature.

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Recital 4f					
14f			(4f) However, the reporting and recognition of occupational cancers as occupational diseases are uneven, due, in particular, to a long latency between the exposure to dangerous substances and the diagnosis of the resulting disease, the multifactorial nature of cancer and also to complex procedures for the official recognition of an illness as work-related and for the obtaining of compensation. Data from work-related health problems are often lacking, unreliable or insufficient. Further efforts are therefore needed to improve reporting, prevention, diagnosis, early recognition and compensation of occupational diseases, as well as better medical		To be considered by the Council <u>EP compromise proposal on recital 4f</u> (row 14f): However, the reporting and recognition of occupational cancers as occupational diseases are uneven, due, in particular, to a long latency between the exposure to dangerous substances and the diagnosis of the resulting disease, the multifactorial nature of cancer and complex procedures for the official recognition of an illness as work-related and for the obtaining of compensation. Data from work-related health problems are often lacking, unreliable or insufficient. It is strongly recommended that Member States ensure that all cases of occupational diseases are

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			monitoring throughout life with robust diseases and exposures registries.		reported and that they ~~to~~ introduce a system for the collection of information or data. Further efforts are therefore needed to improve reporting, prevention, diagnosis, early recognition and compensation of occupational diseases, as well as better medical monitoring throughout life with robust diseases and exposures registries.
Recital 4g					
14g			(4g) Swipe testing in cancer care are rare which means that significant risks of exposure are not identified. If swipe tests were performed systematically, many risks would be identified. The use of such tests should therefore be added to Article 3 of Directive 2004/37/EC with regard to risk assessment.		

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Recital 5					
15	(5) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and should also be based on a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is	(5) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and should also be based on a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is	(5) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC ~~in the light of~~ efusing a risk-based methodology. Binding occupational exposure limit values should be evidence-based and established on the basis of all available information, including ~~new~~ updated scientific and technical data ~~and should also be based on~~ , a thorough assessment of the socioeconomic impact and ~~the~~ availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as	(5) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and should also be based on a thorough assessment of the ~~socioeconomicsocio-economic~~ impact and availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly	Reprotoxic Risk-based methodology Linguistic changes are preliminary agreed: "up-to-date" (for consistency reason) "the" "Socio-economic" <u>Compromise proposal (3rd sentence):</u> It is important that such ~~That information should~~ include, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH) and other sources of scientific information, adequately robust and in the public domain such as monographs of the International Agency for

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	valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens.	valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens.	opinions of the Advisory Committee on Safety and Health at Work (ACSH) and monographs of the International Agency for Research on Cancer (IARC). Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens, mutagens and reprotoxic substances ~~and mutagens~~ .	available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens.	Research on Cancer (IARC). EP will assess the proposal.
Recital 6					
16	(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens or mutagens to a shorter reference period, in general fifteen minutes time-	(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens or mutagens to a shorter reference period, in general fifteen minutes time-	(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens, mutagens and reprotoxic substances ~~or mutagens~~ to a shorter	(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens or mutagens to a shorter reference period, in general fifteen minutes time-	Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.	weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.	reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.	weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.	
Recital 7					
17	(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.	(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.	(7) It is also necessary to consider ~~other~~ absorption pathways other than inhalation of all carcinogens, mutagens and reprotoxic substances and mutagens , including the possibility of uptake through the skin, in order to ensure the best possible level of protection.	(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. Further notations for hazardous substances and compounds can be found in Regulation (EC) No 1272/2008.¹ 1. 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	Reprotoxic Preliminary agreed: “others” Rows 11c+17: EP could accept the Council amendment on reciprocal basis with Council acceptance for row 11c.

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
				repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008).	
Recital 7a					
17a			(7a) In the workplace, workers are often exposed to a cocktail of hazardous substances, which can increase risks and cause adverse health effects. In the case of exposure to a combination of substances acting by the same mode of action or at the same target cell or tissue, it is necessary to adapt the implementation of their possible limit values to take into account the combined effects.		
Recital 8					
18	(8) The assessment of health effects of the carcinogens subject to this Directive was based on the relevant scientific expertise	(8) The assessment of health effects of the carcinogens subject to this Directive was based on the relevant scientific expertise	(8) The assessment of health effects of the carcinogens subject to this Directive was based on the relevant scientific expertise	(8) The assessment of health effects of the carcinogens subject to this Directive was based on the relevant scientific expertise	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	from the RAC. Pursuant to a Service Level Agreement signed by DG Employment, Social Affairs and Inclusion and ECHA, RAC provides scientific evaluations on the toxicological profile of each of the selected priority chemical substances in relation to their adverse health effects on workers.	from the RAC. Pursuant to a Service Level Agreement signed by DG Employment, Social Affairs and Inclusion and ECHA, RAC provides scientific evaluations on the toxicological profile of each of the selected priority chemical substances in relation to their adverse health effects on workers.	from the RAC. Pursuant to a Service Level Agreement signed by DG Employment, Social Affairs and Inclusion and ECHA, RAC provides scientific evaluations on the toxicological profile of each of the selected priority chemical substances in relation to their adverse health effects on workers.	~~from~~ provided by the RAC. Pursuant to a Service Level Agreement signed by DG Employment, Social Affairs and Inclusion and ECHA, RAC provides scientific evaluations on the toxicological profile of each of the selected priority chemical substances in relation to their adverse health effects on workers.	
Recital 9					
19	(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council ¹ and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen.	(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council ¹ and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen.	(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council ¹ and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen.	(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council ¹ and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen.	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	Acrylonitrile can also be absorbed through the skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring. 1. Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272.	Acrylonitrile can also be absorbed through the skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring. 1. Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272.	Acrylonitrile can also be absorbed through the skin. Acrylonitrile is acutely toxic and causes neurotoxicity, local irritation of skin, eyes and respiratory tract, and skin sensitisation. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring. 1. Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272.	Acrylonitrile can also be absorbed through the skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring. 1. 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- Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272 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). [...]	
Recital 10					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
20	(10) With regard to acrylonitrile, a limit value of 1 mg/m ³ (0.45 ppm) and a short-term limit value of 4 mg/m ³ (1.8 ppm) may be difficult to be complied with in the short term. A transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply.	(10) With regard to acrylonitrile, a limit value of 1 mg/m ³ (0.45 ppm) and a short-term limit value of 4 mg/m ³ (1.8 ppm) may be difficult to be complied with in the short term. A transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply.	(10) With regard to acrylonitrile, a limit value of 1 mg/m ³ (0.45 ppm) and a short-term limit value of 4 mg/m ³ (1.8 ppm) may be difficult to be complied with in the short term. A transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply. Exposure should be reduced as far as technically possible below those limit values.	(10) With regard to acrylonitrile, a limit value of 1 mg/m ³ (0.45 ppm) and a short-term limit value of 4 mg/m ³ (1.8 ppm) may be difficult to be complied with in the short term. A transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values ~~shall~~ should apply.	Lawyer linguists: should/shall
Recital 11					
21	(11) Nickel compounds meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is	(11) Nickel compounds meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is	(11) Nickel compounds meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is	(11) Nickel compounds meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	possible, on the basis of the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to nickel compounds at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of the nickel compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.	possible, on the basis of the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to nickel compounds at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of the nickel compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.	possible, on the basis of the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to nickel compounds at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of the nickel compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.	possible, on the basis of the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to nickel compounds at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of the nickel compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.	
Recital 12					
22	(12) With regard to nickel compounds, limit values of 0.01 mg/m ³ for the respirable fraction and 0.05 mg/m ³ for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including	(12) With regard to nickel compounds, limit values of 0.01 mg/m ³ for the respirable fraction and 0.05 mg/m ³ for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including	(12) With regard to nickel compounds, based on a consensus between the social partners in the ACSH , limit values of 0.01 mg/m ³ for the respirable fraction and 0.05 mg/m ³ for the inhalable fraction are introduced. According to	(12) With regard to nickel compounds, limit values of ~~0.01~~ 0,01 mg/m ³ for the respirable fraction and 0.05 mg/m ³ for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m³ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU¹. 1. Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.	specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m³ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU¹. 1. Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.	the RAC, the available information on the mechanisms of genotoxicity and cancer support a mode-of-action based threshold for carcinogenic effects. For that reason, the RAC proposed an occupational exposure limit of 0.005 mg/m³ for the respirable fraction and 0.03 mg/m³ for the inhalable fraction under which no significant residual cancer risk is expected for workers. Those values may be difficult to be complied with in a number of sectors or processes, including specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional	specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of ~~0.1~~0.1 mg/m³ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU¹. 1. Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398	Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398	period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m³ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU¹. Exposure should be reduced as far as technically possible below the limit value introduced and, when possible, below the limit value proposed by the RAC. 1. Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398	Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398 (OJ L 345, 27.12.2017, p. eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L239887). [...]	
Recital 12a					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
22a			(12a) The green economy is expected to expand in the context of the European Green Deal. It is important to continue to ensure and strengthen occupational safety and health aspects when creating new jobs. Nickel compounds play a considerable role in the development of green alternatives to fossil fuels. As the need for nickel compounds is expected to grow, it is essential to protect workers, ensure the full and effective implementation of the occupational exposure limit values to that chemical agent.		
Recital 13					
23	(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore	(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore	(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore	(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore	Benzene

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.	carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.	carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data no later than 1 January 2030 in accordance with the ACSH opinion and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, also agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.	a carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.	
Recital 14					
24	(14) With regard to benzene, a revised limit value of 0.2 ppm (0.66 mg/m ³) may be difficult to be complied with in some sectors in the short term. A	(14) With regard to benzene, a revised limit value of 0.2 ppm (0.66 mg/m ³) may be difficult to be complied with in some sectors in the short term. A	(14) With regard to benzene, based on a consensus between the social partners in the ACSH , a revised limit value of 0.2 ppm (0.66	(14) With regard to benzene, a revised limit value of ~~0.2~~ 0,2 ppm (~~0.66~~ 0,66 mg/m ³) may be difficult to be complied with in some sectors in the	Benzene

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	transitional period of 4 years after entry into force of this Directive should be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m ³) should apply.	transitional period of 4 years after entry into force of this Directive should be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m ³) should apply.	mg/m ³) should be introduced. According to the RAC, a mode-of-action-based threshold for chromosomal damage in workers can be used to establish an occupational exposure limit for carcinogenicity, which is considered to have no significant residual cancer risk and to avoid other adverse effects. For this reason, the RAC proposed an Occupational Exposure limit of 0.05 ppm (0.16mg/m³). Since it may be difficult to be complied with in some sectors in the short term-, a transitional period of 4 years after entry into force of this Directive should be introduced. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m³) should apply. Exposure should be reduced as far as technically possible below the limit value introduced and, when possible, below	short term. A transitional period of 4 years after entry into force of this Directive should therefore be introduced. ~~From two years up to four~~ As a transitional measure, the limit value of 1 ppm (3,25 mg/m³) provided for in Directive (EU) 2019/130 should continue to apply until [OJ: the first 2 years after entry into force, a of this Directive] and a new transitional limit value of 0.50,5 ppm (1.65 mg/m³) should then apply until [OJ: the second 2 years after entry into force of this Directive].	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			the limit value proposed by the RAC.		
Recital 14a					
24a			(14a) The limit value for respirable crystalline silica dust (respirable fraction) set out in Annex III to Directive (EU) 2017/2398 should be revised in the light of the Commission's evaluations pursuant to Directive 2004/37/EC and recent scientific and technical data.		Silica
Recital 14b					
24b			(14b) Cobalt and cobalt compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of		Cobalt

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to cobalt and cobalt compounds at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of cobalt and its compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.		
Recital 14c					
24c			(14c) Hazardous Medicinal Products can cause adverse health effects, such as certain types of cancer and reproductive disorders, in workers who are exposed to them in the course of		HMP

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			work involving their preparation, administration, or disposal. Hazardous Medicinal Products affect workers who handle them directly or indirectly. Such workers include healthcare workers using cytostatic or cytotoxic drugs to treat cancer patients in hospitals or at home and workers who carry out activities relating to the cleaning, transport, laundry, or the waste disposal of hazardous drugs or of material contaminated by such drugs. It is therefore important to protect all workers by including relevant pharmacotherapeutic groups of Hazardous Medicinal Products in Annex I to Directive 2004/37/EC. The reduction and replacement requirements laid down in Article 4 of that Directive do not apply to		

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			Hazardous Medicinal Products because they are essential to treat patients. The other provisions of that Directive, in particular Articles 5 to 18a thereof, as amended by this Directive, apply to workers who are exposed to Hazardous Medicinal Products.		
Recital 14d					
24d			(14d) The use at the workplace or while performing job-related duties, of any carcinogens, mutagens or reprotoxic substances, including those referred to in the annexes to Directive 2004/37/EC, as amended by this Directive, should be reported to the national authorities responsible for supervising workers' health. When deciding what substances to report, Member States should take into account the		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC.		
Recital 15					
25	(15) The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all priority substances concerned by this Directive, recommended one or several binding occupational exposure limit values for each of them, as well as notations.	(15) The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all priority substances concerned by this Directive, recommended one or several binding occupational exposure limit values for each of them, as well as notations.	(15) The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all priority substances concerned by this Directive, recommended one or several binding occupational exposure limit values for each of them, as well as notations.	(15) The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all priority substances concerned by this Directive, recommended one or several binding occupational exposure limit values for each of them, as well as notations, where appropriate.	COM proposal to be changed if substances added from EP report
Recital 15a					
25a			(15a) While maintaining		For the Council to consider, including."microenterprise"

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			equal protection levels for all the workers, it is important to ensure and facilitate operational feasibility and compliance and avoid disproportionate effect on microenterprises and SMEs, also through the assessment of the transposition impact on SMEs, and to take all necessary actions to ensure the safety and health of workers are protected no matter the size of the enterprise. Against that background, specific measures such as incentives and digital tools could help them to better comply with the obligations laid down in the Directive 2004/37/EC. In that regard, the social partners and the European Agency for Health and Safety at Work have an important role to play, in particular to help SMEs assess the risks for their workforce and implement adequate		<u>Compromise proposal row 25a (recital 15a):</u> “While maintaining equal protection levels for all the workers, it is important to ensure and facilitate operational feasibility and compliance, and to avoid a disproportionate effect on microenterprises and SMEs, (---), and to take all necessary actions to ensure that the safety and health of workers are protected regardless of (...) the size of the enterprise. [...] The social partners and (---); the European Agency for Safety and Health at work, subject to Article 2 of Regulation 2019/126/EC, have an important role to play [...] with regard to assisting help microenterprises and SMEs, in particular with regard to assessing (---) the risks of exposure to the substances falling within the scope of this Directive on their workforce and implementing adequate

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			protective measures.		protective measures. “
Recital 16					
26	(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006¹. 1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907.	(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006¹. 1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907.	(16) The limit values established in this Directive are to be kept under ~~regular~~ongoing scrutiny and regular review including making legislative proposals, if appropriate, to ensure consistency with Regulation (EC) No 1907/2006¹. 1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907.	(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006¹. In particular, with regard to benzene, the Commission, in close cooperation with the Advisory Committee for Safety and Health,² will assess the feasibility of a further reduction of the BOEL, taking into account the RAC opinion of 2018 and any new relevant information. 1. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals-~~Available at: https://eur-lex.europa~~ (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and	Benzene

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
				repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907 1). 2. OJ C 218, 13.9.2003, p. 1	
Recital 17					
27	(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the	(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the	(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens, mutagens or reprotoxic substances or ~~mutagens~~ at work, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as	(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the	Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.	Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.	set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.	Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.	
Recital 18					
28	(18) Given that this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.	(18) Given that this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.	(18) Given that this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.	(18) ~~Given that~~ Since this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.	
Recital 18a					
28a			(18a) Articles 153, 154 and 155 of the Treaty on the Functioning of the European Union (TFEU) establish the scope and authority of the social partners to negotiate and enforce agreements		<u>Council to consider:</u> <u>EP compromise proposal:</u> “Articles 153, 154 and 155 of the Treaty on the Functioning of the European Union (TFEU) provide for a (---) role for (---) Social Partners at

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			relating to occupational health and safety and the Charter of Fundamental Rights of the European Union (Charter) ensures, in particular, the fundamental right to life (Article 2 of the Charter) and the right to fair and just working conditions with respect to health, safety and dignity (Article 31(1) of the Charter).		the Union level in[..] negotiating and enforcing agreements relating to occupational health and safety. Furthermore, the Charter of Fundamental Rights of the European Union (Charter) ensures; ~~(...)~~ the ~~(...)~~ right to life (Article 2 of the Charter) and the right to working conditions which respect workers' ~~(...)~~ health, safety and dignity (Article 31(1) of the Charter).”.
Recital 19					
G 29	(19) Directive 2004/37/EC should therefore be amended accordingly,	(19) Directive 2004/37/EC should therefore be amended accordingly,	(19) Directive 2004/37/EC should therefore be amended accordingly,	(19) Directive 2004/37/EC should therefore be amended accordingly,	G
Formula					
G 30	HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:	G
Article 1					
31					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	Article 1	Article 1	Article 1	Article 1 Amendment of Directive 2004/37/EC	Rows for lawyer linguists (31, 33, 37, 39)
Article 1, point -1 (Directive 2004/37/EC, Title)					
31a		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)	(-1) The title of Directive 2004/37/EC is replaced by the following: "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, mutagens or reprotoxic substances at ~~or mutagens at~~ work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)"		Reprotoxic
Article 1, point -1 a (Directive 2004/37/EC Article 1 – paragraph 1 – subparagraph 1)					
31b		1. This Directive has as its aim the protection of workers against risks to	(-1a) In Article 1(1), the first paragraph is replaced by the following:		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
		their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work.	" 1. ~~4.~~ This Directive has as its aim the protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens, ~~or~~ mutagens or reprotoxic substances at work."		
Article 1, point 1 -b (Directive 2004/37/EC Article 2 – point b a (new))					
31c			(-1b) In Article 2, the following point is inserted: "(ba) 'reprotoxic substance' means: a substance or mixture which meets the criteria for being classified as toxic to reproduction category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008;"		Reprotoxic
Article 1, point -1 c (Directive 2004/37/EC Article 2 – point c (new))					
31d		(c) 'limit value' means,	(-1c) In Article 2, point (c)		

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
		unless otherwise specified, the limit of the time-weighted average of the concentration for a 'carcinogen or mutagen' in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III to this Directive.	is replaced by the following: "(c) ' ~~(e)~~ 'limit value'" means, unless otherwise specified, the limit of the time-weighted average of the concentration for a ' ~~'carcinogen, mutagen or reprotoxic substance'~~ in ~~or mutagen'~~ in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III to this Directive."		Reprotoxic
Article 1, point -1 d (Directive 2004/37/EC Article 2 – point c a (new))					
31e			(-1d) In Article 2, the following point is added: "(ca) 'risk-based limit value' means: a limit value set at an exposure level corresponding to a risk of developing an adverse health effect (e.g. cancer) in the range between an upper and a lower risk level, which is		Risk-based methodology

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			to be set in accordance with the procedure laid down in Article 153(2) TFEU."		
Article 1, point 1 e (Directive 2004/37/EC Article 3 – paragraph 1)					
31f		1. This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens or mutagens as a result of their work.	(-1e) In Article 3, paragraph 1 is replaced by the following: "1. ~~1.~~ This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens, mutagens or reprotoxic substances or mutagens as a result of their work."		Reprotoxic
Article 1, point -1 f (Directive 2004/37/EC Article 3 – paragraph 2 – subparagraph 1)					
31g		In the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay	(-1f) In Article 3(2), the first subparagraph is replaced by the following: "In the case of any activity likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances; or mutagens , the nature, degree and duration of		Reprotoxic Risk-based methodology

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
		down the measures to be taken. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens or mutagens. The employer shall supply the authorities responsible at their request with the information used for making the assessment.	workers' exposure shall be determined by way of a systematic risk assessment , in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens, mutagens or reprotoxic substances or mutagens . The employer shall supply the authorities responsible at their request with the information used for making the assessment."		
Article 1, point -1 g (Directive 2004/37/EC Article 3 – paragraph 4)					
31h		4. When the risk assessment is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at	(-1g) In Article 3, paragraph 4 is replaced by the following: "4. 4-When the risk assessment is carried out, employers shall give particular attention to any		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
		particular risk and shall, inter alia, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens or mutagens.	effects concerning the health or safety of workers at particular risk and shall, inter alia, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens, mutagens or reprotoxic substances or mutagens. "		
Article 1, point -1 h (Directive 2004/37/EC Article 4 – paragraph 1)					
31i		1. The employer shall reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.	~~1. The employer shall reduce the use of a~~ (-1h) In Article 4, paragraph 1 is replaced by the following: "1. Where a carcinogen, mutagen or reprotoxic substance is present or mutagen at the place of work, in workplace, the employer shall reduce its use, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use,		Reprotoxic HMP

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			is not dangerous or is less dangerous to workers' health or safety, as the case may be. This paragraph shall not apply to the use of hazardous medicinal products set out in Annex I."		
Article 1, point -1 i (Directive 2004/37/EC Article 5 – paragraph 2)					
31j		2. Where it is not technically possible to replace the carcinogen or mutagen by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system.	(-1i) In Article 5, paragraph 2: is replaced by the following: "2. Where it is not technically possible to replace the carcinogen, mutagen or reprotoxic substance or ~~mutagen~~ by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen, mutagen or reprotoxic substance or ~~mutagen~~ is, in so far as is technically possible, manufactured and used in a closed		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			system."		
Article 1, point -1 j (Directive 2004/37/EC Article 5 – paragraph 4)					
31k		4. Exposure shall not exceed the limit value of a carcinogen as set out in Annex III.	(-1j) In Article 5, paragraph 4 is replaced by the following: "4. 4-Exposure shall not exceed the limit value of a carcinogen, mutagen or reprotoxic substance as set out in Annex III. In the case of exposure to a combination of substances acting by the same mode of action or at the same target cell or tissue, the implementation of the possible limit values of those substances shall be adapted to take into account the combined effects."		
Article 1, point - 1 k (Directive 2004/37/EC Article 5 – paragraph 5 – introductory part)					
31l		5. Wherever a carcinogen or mutagen is used, the employer shall apply all the following measures:	(-1k) In Article 5(5), the introductory part is replaced by the following: "5. 5-Wherever a carcinogen, mutagen or		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			reprotoxic substance ~~or mutagen~~ is used, the employer shall apply all the following measures:"		
Article 1, point -1 l (Directive 2004/37/EC Article 5 – paragraph 5 – point a)					
31m		(a) limitation of the quantities of a carcinogen or mutagen at the place of work;	(-1l) In Article 5(5), point (a) is replaced by the following: "(a) ~~(a)~~ limitation of the quantities of a carcinogen ~~or mutagen~~, mutagen or reprotoxic substance at the place of work;"		Reprotoxic
Article 1, point -1m (Directive 2004/37/EC Article 5 – paragraph 5 – point c)					
31n		(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work;	(-1m) In Article 5(5), point (c) is replaced by the following: "(c) ~~(c)~~ design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens, mutagens or reprotoxic substances ~~or mutagens~~ into the place of work;"		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Article 1, point -1n (Directive 2004/37/EC Article 5 – paragraph 5 – point d)					
31o		(d) evacuation of carcinogens or mutagens at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;	(-1n) In Article 5(5), point (d) is replaced by the following: " ~~(d)~~ evacuation of carcinogens, mutagens or reprotoxic substances at ~~or mutagens at~~ source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;"		Reprotoxic
Article 1, point - 1 o (Directive 2004/37/EC Article 5 – paragraph 5 – point e)					
31p		(e) use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;	(-1o) In Article 5(5), point (e) is replaced by the following: " ~~(e)~~ use of existing appropriate procedures for the measurement of carcinogens, mutagens or reprotoxic substances, in ~~or mutagens, in~~ particular for the early		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			detection of abnormal exposures resulting from an unforeseeable event or an accident;"		
Article 1, point -1 p (Directive 2004/37/EC Article 5 – paragraph 5 – point i a (new))					
31q			(-1p) In Article 5(5), the following point is inserted: "(ia) ensure that personal protective equipment is provided;"		EP suggested to change Art. 5 (5) g as following: "Collective and individual protection measures."
Article 1, point -1 q (Directive 2004/37/EC Article 5 – paragraph 5 – point j)					
31r		(j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens or mutagens;	(-1q) In Article 5(5), point (j) is replaced by the following: "(j) ~~(j)~~ demarcation of risk areas and use of adequate warning and safety signs including ~~'no~~ 'no smoking-' signs in areas where workers are exposed or likely to be exposed to carcinogens, mutagens or reprotoxic substances or ~~mutagens~~;"		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Article 1, point -1 r (Directive 2004/37/EC Article 5 – paragraph 5 – point m a (new))					
31s			(-1r) In Article 5(5), the following point is added: "(ma) in accordance with Directive 92/85/EC, take the necessary measures to ensure that pregnant workers, workers who have recently given birth and workers who are breastfeeding are duly protected and are in no circumstances required to carry out activities which could jeopardise their safety or health."		
Article 1, point -1 s (Directive 2004/37/EC Article 6 – paragraph 1– point a)					
31t		(a) the activities and/or industrial processes carried out, including the reasons for which carcinogens or mutagens are used;	(-1s) In the first paragraph of Article 6, point (a) is replaced by the following: "(a) ~~(a)~~ the activities and/or industrial processes carried out, including the reasons for which carcinogens, mutagens or		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			reprotoxic substances ~~or mutagens~~ are used;"		
Article 1, point -1 t (Directive 2004/37/EC Article 6 – paragraph 1 – point b)					
31u		(b) the quantities of substances or mixtures manufactured or used which contain carcinogens or mutagens;	(-1t) In the first paragraph of Article 6, point (b) is replaced by the following: "(b) ~~(b)~~ the quantities of substances or mixtures manufactured or used which contain carcinogens, ~~or~~ mutagens or reprotoxic substances ;"		Reprotoxic
Article 1, point -1 u (Directive 2004/37/EC Article 10 – paragraph 1 – introductory part)					
31v		1. Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens or mutagens, to take appropriate measures to ensure that:	(-1u) In Article 10(1), the introductory part is replaced by the following: "1. ~~1.~~ Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, mutagens or reprotoxic substances ~~or mutagens~~ , to take appropriate		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			measures to ensure that:"		
Article 1, point -1 v (Directive 2004/37/EC Article 10 – paragraph 1 – point a)					
31w		(a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens or mutagens;	(-1v) In Article 10(1), point (a) is replaced by the following: "(a) ~~(a)~~ workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens or reprotoxic substances ~~or mutagens~~ ;"		Reprotoxic
Article 1, point -1 w (Directive 2004/37/EC Article 11 – paragraph 1 – subparagraph 2 – indents 1 and 2)					
31x		— adapted to take account of new or changed risk, and – repeated periodically if necessary.	(-1 w) In the second subparagraph of Article 11(1), the indents are replaced by the following: — —adapted to take account of new or changed risk,~~and~~ – provided periodically in healthcare settings to all workers who are exposed to carcinogens, mutagens		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			or reprotoxic substances, in particular where new drugs occur, – provided —repeated periodically in other settings if necessary."		
Article 1, point -1 x (Directive 2004/37/EC Article 11 – paragraph 2)					
31y		2. Employers shall inform workers of installations and related containers containing carcinogens or mutagens, ensure that all containers, packages and installations containing carcinogens or mutagens are labelled clearly and legibly, and display clearly visible warning and hazard signs.	(-1x) In Article 11, paragraph 2 is replaced by the following: "2. ~~2.~~ Employers shall inform workers of installations and related containers containing carcinogens, mutagens or reprotoxic substances or ~~mutagens~~, ensure that all containers, packages and installations containing carcinogens, mutagens or reprotoxic substances or ~~mutagens~~ are labelled clearly and legibly, and display clearly visible warning and hazard signs."		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Article 1, point -1 y (Directive 2004/37/EC Article 14 – paragraph 3 – subparagraph 1)					
31z		3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens or mutagens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.	(-1y) In Article 14(3), the first subparagraph is replaced by the following: "3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, mutagens or reprotoxic substances or mutagens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance. "		Reprotoxic
Article 1, point - 1 z (Directive 2004/37/EC Article 14 – paragraph 8 – subparagraph 1)					
31aa		8. All cases of cancer identified in accordance with national laws and/or practice as resulting from occupational exposure to a carcinogen or mutagen shall be notified to the competent authority.	(-1z) In Article 14(8), the first subparagraph is replaced by the following: "8. ~~8.~~ All cases of cancer and reproductive disorder identified in accordance with national laws and/or practice as resulting from occupational exposure to a		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			carcinogen, mutagen or reprotoxic substance ~~or mutagen~~ shall be notified to the competent authority. The Member States shall include the information referred to in this paragraph in their implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC."		
Article 1, point - 1 aa (Directive 2004/37/EC Article 15 – paragraph 2 a (new))					
31ab			(-1aa) In Article 15, the following paragraph is added: "2a. The Member States shall provide the Commission with the information referred to in Article 14(8) as part of the implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC."		
Article 1, point -1 ab (Directive 2004/37/EC Article 16 – paragraph 1)					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
31ac		1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.	(-1ab) In Article 16, paragraph 1 is replaced by the following: "1. The European Parliament and ~~the~~ Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty 153(2) TFEU, set out risk-based limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens, ~~or~~ mutagens or reprotoxic substances for which this is possible, and, where necessary, other directly related provisions."		Reprotoxic Risk-based methodology
Article 1, point -1 ac (Directive 2004/37/EC Article 17 – paragraph 1)					
31ad		The Commission is empowered to adopt delegated acts in accordance with Article 17a to make strictly technical amendments to	(-1 ac) In Article 17, the first paragraph is replaced by the following: "The Commission is empowered to adopt delegated		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
		Annex II, in order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens or mutagens.	acts in accordance with Article 17a to make strictly technical amendments to Annex II, in order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens, mutagens or reprotoxic substances or ~~mutagens.~~ "		
Article 1, point -1 ad (Directive 2004/37/EC Article 18a – paragraph 2 a (new))					
31ae			(-1ad) In Article 18a, the following paragraph is inserted after the second paragraph: "No later than 31 December 2021, the Commission shall, taking into account the existing recommendations from different agencies, stakeholders and the World Health Organization on priority carcinogens, mutagens and reprotoxic substances for which limit values are		Reprotoxic

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			needed, and after consulting the ACSH, present an action plan to achieve occupational exposure limits values for at least 25 substances, groups of substances or process-generated substances additional to those referred to in this Directive. No later than 31 December 2024, the Commission shall, taking into account that action plan, the latest developments in scientific knowledge, and after consulting of the ACSH, present a legislative proposal."		
Article 1, point - 1ae (Directive 2004/37/EC Article 18a – paragraph 2 b (new))					
31af			(-1ae) In Article 18a, the following paragraph is inserted after the second paragraph: "No later than 1 March 2022, the Commission shall, taking into account the latest developments in		HMP

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			scientific knowledge, and after appropriate consultation of relevant stakeholders, in particular health practitioners and health professionals, develop a definition of Hazardous Medicinal Products and establish the list of substances covered by the related entry in Annex I. The Commission shall review that list every two years. No later than 1 December 2022, the Commission shall, after the appropriate consultation of relevant stakeholders, prepare Union guidelines and standards of practice for the preparation, administration, and disposal of Hazardous Medicinal Products. Those guidelines and standards shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA) and shall be disseminated in		

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			all Member States by the relevant competent authorities. The consultations undertaken to develop the definition, list, guidelines and standards shall be transparent. The declarations of interests of stakeholders and experts shall be made public in a timely manner."		
Article 1, point -1af (Directive 2004/37/EC Article 18a – paragraph 2 c (new))					
31ag			(-1af) In Article 18a, the following paragraph is inserted after the second paragraph: "No later than 1 June 2022, the Commission shall, taking into account the existing methodology to set limit values for carcinogens in some Member States and the opinion of the ACSH, define the upper and lower risk levels referred to in Article 2. No later		Risk-based methodology

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			than 1 December 2022, the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines on the methodology establishing risk-based limit values under this Directive. Those guidelines shall be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities."		
Article 1, point -1 ag (Directive 2004/37/EC Article 18a – paragraph 4 a (new))					
31ah			(-1 ag) In Article 18a, the following paragraph is added: "No later than 1 December 2022, the Commission shall, taking into account the latest developments in scientific knowledge and the opinion of RAC, and after appropriate consultation of relevant stakeholders,		

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			prepare Union guidelines on how the implementation of the limit values referred to in Article 5(4) are to be adapted in the case of exposure to a combination of substances. Those guidelines shall be published on the EU-OSHA website and be disseminated in all Member States by the relevant competent authorities."		
Article 1, point -1 ah (Directive 2004/37/EC Article 18a – paragraph 4 b (new))					
31ai			(-1ah) In Article 18a, the following paragraph is added: "No later than 31 December 2023, the Commission shall, after consulting the ACSH and taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, present a legislative		Cobalt

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			proposal to introduce the limit value for cobalt and cobalt compounds."		
Article 1, point -1 ai (Directive 2004/37/EC Article 18a – paragraph 4 c (new))					
31aj			(-1ai) In Article 18a, the following paragraph is added: "No later than 1 January 2028, the Commission shall, taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, start evaluating the feasibility of a further reduction of the limit value for benzene. No later than 1 January 2030, the Commission shall propose, where appropriate, necessary amendments and modifications related to that substance."		Benzene
Article 1, point - 1 aj (Directive 2004/37/EC Article 18a – paragraph 4 d (new))					
31ak					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			(-1aj) In Article 18a, the following paragraph is added: "No later than 1 January 2028, the Commission shall, taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, evaluate the feasibility of a further reduction of the limit value for nickel compounds. No later than 1 January 2030, the Commission shall propose, where appropriate, necessary amendments and modifications related to that substance."		
Article 1, point -1 ak (Directive 2004/37/EC Annex I – point 8 a (new))					
31al			(-1 ak) In Annex I the following point is added: "8a. Work involving exposure to Hazardous Medicinal Products meeting the criteria for		HMP

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			classification as carcinogenic, mutagenic and/or toxic for reproduction category 1A or 1B set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council."		
Article 1, point -1 ak (Directive 2004/37/EC Annex II – point 1)					
31am		1. The doctor and/or authority responsible for the health surveillance of workers exposed to carcinogens or mutagens must be familiar with the exposure conditions or circumstances of each worker.	(-1al) In Annex II, point 1 is replaced by the following: "1. ~~The~~ doctor and/or authority responsible for the health surveillance of workers exposed to carcinogens, mutagens or reprotoxic substances or mutagens must be familiar with the exposure conditions or circumstances of each worker."		Reprotoxic
Article 1, first paragraph					
32	Annex III to Directive	Annex III to Directive	Annex III to Directive	-Annex III to Directive	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	2004/37/EC is amended in accordance with the Annex to this Directive	2004/37/EC is amended in accordance with the Annex to this Directive	2004/37/EC is amended in accordance with the Annex to this Directive	2004/37/EC is amended in accordance with the Annex to this Directive.	
Article 2					
33	Article 2	Article 2	Article 2	Article 2 Transposition	Rows for lawyer linguists (31, 33, 37, 39)
Article 2(1), introductory part					
34	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [two years] after the date of entry into force of this Directive at the latest. They shall forthwith communicate to the Commission the text of those provisions.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [two years] after the date of entry into force of this Directive at the latest. They shall forthwith communicate to the Commission the text of those provisions.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [two years] after the date of entry into force of this Directive at the latest. They shall forthwith communicate to the Commission the text of those provisions.	1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... [two years] after the date of entry into force of this Directive ~~at the latest~~ . They shall ~~forthwith~~ immediately communicate ~~to the Commission~~ the text of those provisions measures to the Commission.	
Article 2(1), first paragraph					
35	When Member States adopt	When Member States adopt	When Member States adopt	When Member States adopt	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	those provisionsmeasures, 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.	
Article 2(2)					
36	2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	
Article 3					
37	Article 3	Article 3	Article 3	Article 3 Entry into force	Rows for lawyer linguists (31, 33, 37, 39)
Article 3, first paragraph					
38	This Directive shall enter into force on the twentieth day following that of its	This Directive shall enter into force on the twentieth day following that of its	This Directive shall enter into force on the twentieth day following that of its	This Directive shall enter into force on the twentieth day following that of its	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	publication in the Official Journal of the European Union.	publication in the Official Journal of the European Union.	publication in the Official Journal of the European Union.	publication in the Official Journal of the European Union.	
Article 4					
39	Article 4	Article 4	Article 4	Article 4 Addressees	Rows for lawyer linguists (31, 33, 37, 39)
Article 4, first paragraph					
40	This Directive is addressed to the Member States.	This Directive is addressed to the Member States.	This Directive is addressed to the Member States.	This Directive is addressed to the Member States.	
Formula					
41	Done at Brussels,	Done at Brussels,	Done at Brussels,	Done at Brussels,	
Formula					
42	For the European Parliament	For the European Parliament	For the European Parliament	For the European Parliament	
Formula					
43	The President	The President	The President	The President	
Formula					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
44	For the Council	For the Council	For the Council	For the Council	
Formula					
45	The President	The President	The President	The President	
Annex, point (1)					
45a			Treated outside of TTE	1 The Annex to Directive 2004/37/EC is amended as follows: Treated outside of TTE	Treated outside of TTE
Annex, point (1), introductory part					
46	1. In point A of Annex III to Directive 2004/37/EC, the row related to benzene is replaced by the following row:	1. In point A of Annex III to Directive 2004/37/EC, the row related to benzene is replaced by the following row:	1. In point A of Annex III to Directive 2004/37/EC, the row related to benzene is replaced by the following row: Treated outside of TTE	1. in point A of Annex III to Directive 2004/37/EC, the row related to benzene is replaced by the following row: Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 1, Row 1					
47	Name of agent	Name of agent	Name of agent	Name of agent	Treated outside of TTE

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			Treated outside of TTE	Treated outside of TTE	
Annex, point (1), Table 1, Column 1, Row 4					
48	Benzene	Benzene	Benzene Treated outside of TTE	Benzene Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 2, Row 1					
49	EC No ⁽¹⁾	EC No ⁽¹⁾	EC No ⁽¹⁾ Treated outside of TTE	EC No ⁽¹⁾ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 2, Row 4					
50	200-753-7	200-753-7	200-753-7 Treated outside of TTE	200-753-7 Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 3, Row 1					
51	CAS No ⁽²⁾	CAS No ⁽²⁾	CAS No ⁽²⁾ Treated outside of TTE	CAS No ⁽²⁾ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 3, Row 4					
52					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	71-43-2	71-43-2	71-43-2 Treated outside of TTE	71-43-2 Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 4, Row 1					
53	Limit values	Limit values	Limit values Treated outside of TTE	Limit values Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 1, Row 2					
54	8 hours ⁽³⁾	8 hours ⁽³⁾	8 hours ⁽³⁾ Treated outside of TTE	8 hours ⁽³⁾ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 1, Row 3					
55	mg/m ³ ⁽⁵⁾	mg/m ³ ⁽⁵⁾	mg/m ³ ⁽⁵⁾ Treated outside of TTE	mg/m ³ ⁽⁵⁾ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 4, Row 4					
56	0.66	0.66	0.66 Treated outside of TTE	~~0.66~~ 0,66 Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 2, Row 3					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
57	ppm ⁽⁶⁾	ppm ⁽⁶⁾	ppm ⁽⁶⁾ Treated outside of TTE	ppm ⁽⁶⁾ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 5, Row 4					
58	0.2	0.2	0.2 Treated outside of TTE	~~0.2~~ 0,2 Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 3, Row 3					
59	f/ml ⁽⁷⁾	f/ml ⁽⁷⁾	f/ml ⁽⁷⁾ Treated outside of TTE	f/ml ⁽⁷⁾ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 6, Row 4					
60	□	□	□ Treated outside of TTE	□ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 4, Row 2					
61	Short-term ⁽⁴⁾	Short-term ⁽⁴⁾	Short-term ⁽⁴⁾ Treated outside of TTE	Short-term ⁽⁴⁾ Treated outside of TTE	Treated outside of TTE

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Annex, point (1), Table 1, Column 4, Row 3					
62	mg/m ³	mg/m ³	mg/m ³ Treated outside of TTE	mg/m ³ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 7, Row 4					
63	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 5, Row 3					
64	ppm	ppm	ppm Treated outside of TTE	ppm Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 8, Row 4					
65	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 6, Row 3					
66	f/ml	f/ml	f/ml	f/ml	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			Treated outside of TTE	Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 9, Row 4					
67	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 10, Row 1					
68	Notation	Notation	Notation Treated outside of TTE	Notation Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 10, Row 4					
69	Skin ⁽⁸⁾	Skin ⁽⁸⁾	Skin ⁽⁸⁾ Treated outside of TTE	Skin ⁽⁸⁾ Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 11, Row 1					
70	Transitional measures	Transitional measures	Transitional measures Treated outside of TTE	Transitional measures Treated outside of TTE	Treated outside of TTE
Annex, point (1), Table 1, Column 11, Row 4					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
71	The limit value shall apply from four years after entry into force of this Directive. From two years up to four years after entry into force, a limit value of 0.5 ppm (1.65 mg/m ³) shall apply.	The limit value shall apply from four years after entry into force of this Directive. From two years up to four years after entry into force, a limit value of 0.5 ppm (1.65 mg/m ³) shall apply.	The limit value shall apply from four years after entry into force of this Directive. From two years up to four years after entry into force, a limit value of 0.5 ppm (1.65 mg/m ³) shall apply. Treated outside of TTE	~~The Limit value shall apply from four years after the entry into force of this Directive. From two years up to four years after the entry into force, a limit value of 0.5 ppm (1.65 mg/m³) shall apply].~~ Limit value 0,5 ppm (1,65 mg/m³) until [OJ: 4 of this Directive]. Treated outside of TTE	Treated outside of TTE
Annex, point (2), introductory part					
72	2. In point A of Annex III to Directive 2004/37/EC, the following rows are added:	2. In point A of Annex III to Directive 2004/37/EC, the following rows are added:	2. In point A of Annex III to Directive 2004/37/EC, the following rows are added: Treated outside of TTE	2. in point A of Annex III to Directive 2004/37/EC, the following rows are added: Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 1, Row 1					
73	Name of agent	Name of agent	Name of agent Treated outside of TTE	Name of agent Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 1, Row 4					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
74	Acrylonitrile	Acrylonitrile	Acrylonitrile Treated outside of TTE	Acrylonitrile Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 1, Row 5					
75	Nickel compounds	Nickel compounds	Nickel compounds Treated outside of TTE	Nickel compounds Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 2, Row 1					
76	EC No ⁽¹⁾ 1. (JEC No, i.e. Eines, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.	EC No ⁽¹⁾ 1. (JEC No, i.e. Eines, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.	EC No ⁽¹⁾ 1. (JEC No, i.e. Eines, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008. Treated outside of TTE	EC No ⁽¹⁾ 1. (JEC No, i.e. Eines, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008. Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 2, Row 4					
77	203-466-5	203-466-5	203-466-5 Treated outside of TTE	203-466-5 Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 2, Row 5					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
78	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 3, Row 1					
79	CAS No ⁽¹⁾ 1. () CAS No: Chemical Abstract Service Registry Number.	CAS No ⁽¹⁾ 1. () CAS No: Chemical Abstract Service Registry Number.	CAS No ⁽¹⁾ 1. () CAS No: Chemical Abstract Service Registry Number. Treated outside of TTE	CAS No ⁽¹⁾ 1. () CAS No: Chemical Abstract Service Registry Number. Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 3, Row 4					
80	107-13-1	107-13-1	107-13-1 Treated outside of TTE	107-13-1 Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 3, Row 5					
81	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 4, Row 1					
82	Limit values	Limit values	Limit values	Limit values	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			Treated outside of TTE	Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 1, Row 2					
83	8 hours ⁽¹⁾ 1. () Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).	8 hours ⁽¹⁾ 1. () Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).	8 hours ⁽¹⁾ 1. () Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA). Treated outside of TTE	8 hours ⁽¹⁾ 1. () Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA). Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 1, Row 3					
84	mg/m ³ ⁽¹⁾ 1. () mg/m ³ = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).	mg/m ³ ⁽¹⁾ 1. () mg/m ³ = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).	mg/m ³ ⁽¹⁾ 1. () mg/m ³ = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure). Treated outside of TTE	mg/m ³ ⁽¹⁾ 1. () mg/m ³ = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure). Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 4, Row 4					
85	1	1	1 Treated outside of TTE	1 Treated outside of TTE	Treated outside of TTE

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Annex, point (2), Table 2, Column 4, Row 5					
86	0.01 ⁽¹⁾ 0.05() 1. () Respirable fraction, measured as nickel	0.01 ⁽¹⁾ 0.05() 1. () Respirable fraction, measured as nickel	0.01 ⁽¹⁾ 0.05() 1. () Respirable fraction, measured as nickel Treated outside of TTE	~~0.01⁽¹⁾~~ ~~0.050,01⁽¹⁾~~ 0,05 ⁽²⁾ 1. () Respirable fraction, measured as nickel 2. Inhalable fraction, measured as nickel Treated outside of TTE Footnote related to text 0.05: "Inhalable fraction, measured as nickel" was present in the original Commission proposal, but it is not present there due to technical constraints.	Treated outside of TTE
Annex, point (2), Table 2, Column 2, Row 3					
87	ppm ⁽¹⁾ 1. () ppm = parts per million by volume in air (ml/m ³).	ppm ⁽¹⁾ 1. () ppm = parts per million by volume in air (ml/m ³).	ppm ⁽¹⁾ 1. () ppm = parts per million by volume in air (ml/m ³). Treated outside of TTE	ppm ⁽¹⁾ 1. () ppm = parts per million by volume in air (ml/m ³). Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 5, Row 4					
88					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	0.45	0.45	0.45 Treated outside of TTE	~~0.45~~ 0,45 Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 5, Row 5					
89	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 3, Row 3					
90	f/ml (¹) 1. () f/ml = fibres per millilitre.	f/ml (¹) 1. () f/ml = fibres per millilitre.	f/ml (¹) 1. () f/ml = fibres per millilitre. Treated outside of TTE	f/ml (¹) 1. () f/ml = fibres per millilitre. Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 6, Row 4					
91	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 6, Row 5					
92	☐	☐	☐	☐	

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
			Treated outside of TTE	Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 4, Row 2					
93	Short-term (¹) 1. () Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.	Short-term (¹) 1. () Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.	Short-term (¹) 1. () Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified. Treated outside of TTE	Short-term (¹ _____ _____ _____) 1. () Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified. Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 4, Row 3					
94	mg/m ³	mg/m ³	mg/m³ Treated outside of TTE	mg/m³ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 7, Row 4					
95	4	4	4 Treated outside of TTE	4 Treated outside of TTE	Treated outside of TTE

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Annex, point (2), Table 2, Column 7, Row 5					
96	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 5, Row 3					
97	ppm	ppm	ppm Treated outside of TTE	ppm Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 8, Row 4					
98	1.8	1.8	1.8 Treated outside of TTE	~~1.8~~ 1,8 Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 8, Row 5					
99	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 6, Row 3					
100	f/ml	f/ml	f/ml Treated outside of TTE	f/ml Treated outside of TTE	Treated outside of TTE

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
Annex, point (2), Table 2, Column 9, Row 4					
101	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 9, Row 5					
102	☐	☐	☐ Treated outside of TTE	☐ Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 10, Row 1					
103	Notation	Notation	Notation Treated outside of TTE	Notation Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 10, Row 4					
104	Skin ⁽¹⁾ <u>1. () Substantial contribution to the total body burden via dermal exposure possible.</u>	Skin ⁽¹⁾ <u>1. () Substantial contribution to the total body burden via dermal exposure possible.</u>	Skin ⁽¹⁾ <u>1. () Substantial contribution to the total body burden via dermal exposure possible.</u> Treated outside of TTE	Skin ⁽¹⁾ Dermal sensitisation ⁽²⁾ <u>1. ~~()~~ Substantial contribution to the total body burden via dermal exposure possible.</u> 2. The substance can cause sensitisation of the skin.	Treated outside of TTE

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
				Treated outside of TTE	
Annex, point (2), Table 2, Column 10, Row 5					
105	Dermal and respiratory sensitisation ⁽¹⁾ 1. () The substance can cause sensitisation of the skin and of the respiratory tract.	Dermal and respiratory sensitisation ⁽¹⁾ 1. () The substance can cause sensitisation of the skin and of the respiratory tract.	Dermal and respiratory sensitisation ⁽¹⁾ 1. () The substance can cause sensitisation of the skin and of the respiratory tract. Treated outside of TTE	Dermal and respiratory sensitisation ⁽¹⁾ 1. () The substance can cause sensitisation of the skin and of the respiratory tract. Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 11, Row 1					
106	Transitional measures	Transitional measures	Transitional measures Treated outside of TTE	Transitional measures Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 11, Row 4					
107	The limit values shall apply from four years after entry into force of this Directive.	The limit values shall apply from four years after entry into force of this Directive.	The limit values shall apply from four years after entry into force of this Directive. Treated outside of TTE	The limit values shall apply from ~~four~~... [OJ: 4 years after the entry into force of this Directive]. Treated outside of TTE	Treated outside of TTE
Annex, point (2), Table 2, Column 11, Row 5					
108					

	Commission Proposal	COM proposal + base directive	EP Mandate	Council Mandate	Draft Agreement
	The limit value ⁽⁹⁾ shall apply from 18th January 2025 The limit value ⁽¹⁰⁾ shall apply from 18th January 2025. Until then a limit value of 0.1 mg/m³ ⁽¹⁰⁾ shall apply.	The limit value ⁽⁹⁾ shall apply from 18th January 2025 The limit value ⁽¹⁰⁾ shall apply from 18th January 2025. Until then a limit value of 0.1 mg/m³ ⁽¹⁰⁾ shall apply.	The limit value ⁽⁹⁾ shall apply from 18th January 2025 The limit value ⁽¹⁰⁾ shall apply from 18th January 2025. Until then a limit value of 0.1 mg/m³ ⁽¹⁰⁾ shall apply. Treated outside of TTE	The limit value ⁽⁹¹⁰⁾ shall apply from 18th January 2025 The limit value ⁽⁺⁰¹¹⁾ shall apply from 18th January 2025. Until then a limit value of ~~0.10~~ 0.1 mg/m³ ⁽⁺⁰¹¹⁾ shall apply. Treated outside of TTE	Treated outside of TTE

Commission proposal

ANNEX

1. In point A of Annex III to Directive 2004/37/EC, the row related to benzene is replaced by the following row:

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values						Notation	Transitional measures
			8 hours ⁽³⁾			Short-term ⁽⁴⁾				
			mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³	ppm	f/ml		
Benzene	200-753-7	71-43-2	0.66	0.2	–	–	–	–	Skin ⁽⁸⁾	The limit value shall apply from four years after entry into force of this Directive. From two years up to four years after entry into force, a limit value of 0.5 ppm (1.65 mg/m³) shall apply.

2. In point A of Annex III to Directive 2004/37/EC, the following rows are added:

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values						Notation	Transitional measures
			8 hours ⁽³⁾			Short-term ⁽⁴⁾				
			mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³	ppm	f/ml		
Acrylonitrile	203-466-5	107-13-1	1	0.45	–	4	1.8	–	Skin ⁽⁸⁾	The limit values shall apply from four years after entry into force of this Directive.
Nickel compounds	–	–	0.01 ⁽⁹⁾ 0.05 ⁽¹⁰⁾)	–	–	–	–	–	Dermal and respiratory sensitisation ⁽¹¹⁾	The limit value ⁽⁹⁾ shall apply from 18 th January 2025 The limit value ⁽¹⁰⁾ shall apply from 18 th January 2025. Until then a limit value of 0.1 mg/m ³ ⁽¹⁰⁾ shall apply.

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- (¹) EC No, i.e. ~~Einecs~~, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.
- (²) CAS No: Chemical Abstract Service Registry Number.
- (³) Measured or calculated in relation to a reference period of eight ~~hours~~ time-weighted average (TWA).
- (⁴) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
- (⁵) mg/m³ = milligrams per cubic metre of air at 20 °C and 101,3 ~~kPa~~ (760 mm mercury pressure).
- (⁶) ppm = parts per million by volume in air (ml/m³).
- (⁷) f/ml = fibres per millilitre.
- (⁸) Substantial contribution to the total body burden via dermal exposure possible.
- (⁹) ~~Respirable~~ fraction, measured as nickel
- (¹⁰) Inhalable fraction, measured as nickel
- (¹¹) The substance can cause sensitisation of the skin and of the respiratory tract.

EP mandate

Annex – point 1 – introductory part
Directive 2004/37/EC
Annex III – point A – row 4

<i>Present text</i>										
<i>Respirable crystalline silica dust</i>	–	–	0,1	–	–	–	–	–	–	
<i>Amendment</i>										
<i>Respirable crystalline silica dust</i>	–	–	0,05	–	–	–	–	–	–	

Council mandate

The **Annex to Directive 2004/37/EC** is amended as follows:

(1) in point A of Annex III to Directive 2004/37/EC, the row related to benzene is replaced by the following row:

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values						Notation	Transitional measures
			8 hours ⁽³⁾			Short-term ⁽⁴⁾				
			mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³	ppm	f/ml		
Benzene	200-753-7	71-43-2	0,66	0,2	–	–	–	–	Skin ⁽⁸⁾	Limit value 1 ppm (3,25 mg/m³) until [OJ: 2 years after the entry into force]. Limit value 0,5 ppm (1,65 mg/m³) until [OJ: 4 years after the entry into force].

(2) in point A of Annex III to Directive 2004/37/EC, the following rows are added

Name of agent	EC No ⁽¹⁾	CAS No ⁽²⁾	Limit values						Notation	Transitional measures
			8 hours ⁽³⁾			Short-term ⁽⁴⁾				
			mg/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³	ppm	f/ml		
Acrylonitrile	203-466-5	107-13-1	1	0,45	–	4	1,8	–	Skin ⁽⁸⁾ Dermal sensitisation ⁽⁹⁾	The limit values shall apply from ... [OJ: 4 years after the entry into force of this Directive].
Nickel compounds	–	–	0,01 ⁽¹⁰⁾ 0,05 ⁽¹¹⁾	–	–	–	–	–	Dermal and respiratory sensitisation ⁽¹²⁾	The limit value ⁽¹⁰⁾ shall apply from 18 th January 2025 The limit value ⁽¹¹⁾ shall apply from 18 th January 2025. Until then a limit value of 0,1 mg/m ³ ⁽¹¹⁾ shall apply.

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- (1) EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.
- (2) CAS No: Chemical Abstract Service Registry Number.
- (3) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).
- (4) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
- (5) mg/m³ = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
- (6) ppm = parts per million by volume in air (ml/m³).
- (7) f/ml = fibres per millilitre.
- (8) Substantial contribution to the total body burden via dermal exposure possible.
- (9) **The substance can cause sensitisation of the skin.**
- (10) Respirable fraction, measured as nickel
- (11) Inhalable fraction, measured as nickel
- (12) The substance can cause sensitisation of the skin and of the respiratory tract.