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From:	General Secretariat of the Council
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Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates - Four column table

Delegations will find attached the four-column table on the above-mentioned proposal. The four-column table is complemented by an addendum containing the tables from the Annexes of the Commission proposal.

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates

2023/0033(COD)

	Commission Proposal	EP Mandate	9619/23 Council Mandate	Draft Agreement
Formula				
1	2023/0033 (COD)		2023/0033 (COD)	
Proposal Title				
2	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates		Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for **diisocyanates and** lead and its inorganic compounds ~~and diisocyanates~~	
Formula				

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3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Citation 1				
4	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2), point (b), in conjunction with paragraph 1, point (a), thereof,		Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2), point (b), in conjunction with paragraph 1, point (a), thereof,	
Citation 2				
5	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,	
Citation 4				
7	Having regard to the opinion of the European Economic and Social		Having regard to the opinion of the European Economic and Social	

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	Committee,		Committee,	
Citation 5				
8	Having regard to the opinion of the Committee of the Regions,		Having regard to the opinion of the Committee of the Regions,	
Citation 6				
9	Acting in accordance with the ordinary legislative procedure,		Acting in accordance with the ordinary legislative procedure,	
Formula				
10	Whereas:		Whereas:	
Recital 1				
11	(1) The scope of Directive 2004/37/EC of the European Parliament and of the Council[1], was extended by Directive (EU) 2022/431 of the European Parliament and of the Council[2], to cover also reprotoxic substances, including lead and its inorganic compounds. As a result, both Council Directive 98/24/EC[3],		(1) The scope of Directive 2004/37/EC of the European Parliament and of the Council[1], was extended by Directive (EU) 2022/431 of the European Parliament and of the Council[2], to cover also reprotoxic substances, including lead and its inorganic compounds. As a result, both Council Directive 98/24/EC[3],	

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	Annexes I and II to which already cover that chemical agent and its compounds, and Directive 2004/37/EC establish the same occupational exposure limit value and biological limit value for lead and its inorganic compounds. Those limit values do not take into account the latest scientific and technical developments and findings enabling the strengthening of workers' protection against the risk arising from occupational exposure to that dangerous reprotoxicant, as also confirmed by the results of an evaluation carried out in accordance with Article 17a of Council Directive 89/391/EEC[4]. _____ 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). 2. Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 88, 16.3.2022, p. 1). 3. Council Directive 98/24/EC of 7 April		Annexes I and II to which already cover that chemical agent and its compounds, and Directive 2004/37/EC establish the same occupational exposure limit value and biological limit value for lead and its inorganic compounds. Those limit values do not take into account the latest scientific and technical developments and findings enabling the strengthening of workers' protection against the risk arising from occupational exposure to that dangerous reprotoxicant, as also confirmed by the results of an evaluation carried out in accordance with Article 17a of Council Directive 89/391/EEC[4]. _____ 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**, mutagens or reprotoxic substances** ~~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). 2. Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 88, 16.3.2022, p. 1).	

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	1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p 11). 4. Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.06.1989, p.1).		3. Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p 11). 4. Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.06.1989, p.1).	
Recital 1a				
11a		***(1a) Member States should maintain equal protection of all workers and should facilitate the compliance of SMEs and microenterprises with the obligations stemming from this Directive. SMEs and microenterprises, which represent a large majority of enterprises in the Union, have limited financial, technical and human resources. Member States should therefore monitor and report the effects of the implementation of this Directive on SMEs and microenterprises, including any undue administrative tasks, in order to ensure that they are not***		

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		disproportionately affected and have the financial and administrative capacity to comply with the obligations stemming from this Directive. Against that background, specific measures, such as financial and technical support, could help SMEs and microenterprises.		
Recital 2				
12	(2) Pursuant to its Article 1(3), Directive 98/24/EC is to apply to carcinogens, mutagens and reprotoxic substances at work without prejudice to more stringent or specific provisions set out in Directive 2004/37/EC. To ensure legal certainty and avoid ambiguities and possible confusion over the applicable limit values for lead and its inorganic compounds, those Directives should be amended. This will provide for a revised binding occupational exposure limit value and biological limit value in Directive 2004/37/EC only, more specifically its Annexes III and IIIa containing more specific provisions on		(2) Pursuant to its Article 1(3), Directive 98/24/EC is to apply to carcinogens, mutagens and reprotoxic substances at work without prejudice to more stringent or specific provisions set out in Directive 2004/37/EC. **This applies inter alia to Article 10 (4) of Directive 98/24/EC with regard to Annex IIIa of Directive 2004/37/EC.** To ensure legal certainty and avoid ambiguities and possible confusion over the applicable limit values for lead and its inorganic compounds, those Directives should be amended. This will provide for a revised binding occupational exposure limit value and biological limit	

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	reprotoxic substances such as lead and its inorganic compounds. Therefore, the specific provisions setting the occupational exposure limit value for lead and its inorganic compounds in Annex I to Directive 98/24/EC and a biological limit value for lead and its ionic compounds in Annex II to Directive 98/24/EC should be deleted.		value in Directive 2004/37/EC only, more specifically its Annexes III and IIIa containing more specific provisions on reprotoxic substances such as lead and its inorganic compounds. Therefore, the specific provisions setting the occupational exposure limit value for lead and its inorganic compounds in Annex I to Directive 98/24/EC and a biological limit value for lead and its ionic compounds in Annex II to Directive 98/24/EC should be deleted.	
Recital 3				
13	(3) New and revised limit values should be set out in light of available information, including up-to-date scientific evidence and technical data, based on a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the place of work.		(3) New and revised limit values should be set out in light of available information, including up-to-date scientific evidence and technical data, based on a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the place of work.	
Recital 4				
14				

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	(4) In accordance with the recommendations of the Committee for Risk Assessment of the European Chemicals Agency, established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[1], and the Advisory Committee on Safety and Health at Work, limit values for the inhalation route of exposure are usually established in relation to a reference period of an 8-hour time-weighted average (long-term exposure limit values). For certain chemicals, limit values are also set with reference to a shorter reference period, in general a 15-minute time-weighted average (short-term exposure limit values) in order to limit, to the extent possible, the effects arising from short-term exposure. _____ 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 (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		(4) In accordance with the recommendations of the Committee for Risk Assessment of the European Chemicals Agency, established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[1], and the Advisory Committee on Safety and Health at Work, limit values for the inhalation route of exposure are usually established in relation to a reference period of an 8-hour time-weighted average (long-term exposure limit values). For certain chemicals, limit values are also set with reference to a shorter reference period, in general a 15-minute time-weighted average (short-term exposure limit values) in order to limit, to the extent possible, the effects arising from short-term exposure. _____ 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 (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	

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	Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)		Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)	
Recital 5				
15	(5) To ensure a more comprehensive level of protection, it is also necessary to consider absorption pathways other than inhalation for diisocyanates, including the possibility of uptake through the skin. Further notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[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 repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).		(5) ~~To ensure a more comprehensive level of protection, it is also necessary to consider absorption pathways other than inhalation for diisocyanates, including the possibility of uptake through the skin. Further notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[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 repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).~~ moved to recital 10a	
Recital 6				
16	(6) Lead and its inorganic	(6) Lead and its inorganic	(6) Lead and its inorganic	

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	compounds are key occupational reprotoxicants that can affect both fertility and the development of the foetus and meet the criteria for classification as toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and are therefore a reprotoxic substances within the meaning of Article 2, point (ba), of Directive 2004/37/EC.	compounds are key occupational reprotoxicants that can affect both fertility and the development of the foetus and meet the criteria for classification as toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and are therefore a reprotoxic substances within the meaning of Article 2, point (ba), of Directive 2004/37/EC. ***Studies show that lead accounts for around half of all occupational exposure to reprotoxic substances. It is not scientifically possible to identify a level below which exposure to lead and its inorganic compounds would not have adverse health effects for the development of the offspring of female workers of childbearing age. A notation as "non-threshold reprotoxic substance" should therefore be introduced for lead and its inorganic compounds and employers should ensure that the occupational exposure of workers is reduced to as low a level as is technically possible.***	compounds are key occupational reprotoxicants that can affect both fertility and the development of the foetus and meet the criteria for classification as toxic for reproduction (category 1A) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council and are therefore ~~a~~ reprotoxic substances within the meaning of Article 2, point (ba), of Directive 2004/37/EC.	

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Recital 6a				
16a			**(6a) Pursuant to Directive 2004/37/EC, the European Parliament and the Council are to identify, on the basis of the available scientific and technical data, in the notations column of Annex III to that Directive whether a reprotoxic substance is a non-threshold reprotoxic substance or a threshold reprotoxic substance. While the biological limit value of 15 µg Pb/100ml blood recommended by RAC and set out in this Directive, protects the health of workers, it is not scientifically possible to identify a safe level of exposure for lead and its inorganic compounds for the development effects of the offspring. A notation as "non-threshold reprotoxic substance" should therefore be introduced for lead and its inorganic compounds.**	
Recital 7				
17	(7) Oral and inhalation exposure		(7) Oral and inhalation exposure	

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	are both relevant routes for the uptake of lead and its inorganic compounds into the human body. Taking into account the most recent scientific data and new findings with regard to lead and its inorganic compounds, it is necessary to improve the protection of workers exposed to a potential health risk, by reducing both the occupational exposure and biological limit values for lead. Therefore, a revised biological limit value equal to 15 µg/100ml blood, accompanied by a revised occupational exposure limit value equal to 0.03 mg/m^3 as an 8-hour time-weighted average (TWA) should be established.		are both relevant routes for the uptake of lead and its inorganic compounds into the human body. Taking into account the most recent scientific data and new findings with regard to lead and its inorganic compounds, it is necessary to improve the protection of workers exposed to a potential health risk, by reducing both the occupational exposure and biological limit values for lead. Therefore, a revised biological limit value equal to 15 ~~µg/100ml~~**µg Pb/100 ml** blood, accompanied by a revised occupational exposure limit value equal to ~~0.03~~**0,03** mg/m^3 as an 8-hour time-weighted average (TWA) should be established.	
Recital 7a				
17a		***(7a) The Committee for Risk Assessment of the European Chemicals Agency has recommended an occupational exposure limit (OEL) of 4 µg Pb/m3 as an 8-hour time-weighted average (TWA)[1a]. The Committee also recommended a binding***		

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		biological limit value (BLV) of 15 µg Pb/100ml (150 µg Pb/L), but concluded that such a BLV for lead does not protect the future children of female workers of childbearing age exposed. The Committee recommended that the blood-lead level in female workers of childbearing age should not exceed the reference values for the general population not occupationally exposed to lead in the relevant Member State. ***_____*** ***1a*** ***https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037***		
Recital 7b				
17b		***(7b) In its initiative report on a new Union strategic framework on health and safety at work post 2020 (including better protection of workers from exposure to harmful substances, stress at work and repetitive motion injuries) of 9 February 2022, the European Parliament noted that a BLV of 15 µg Pb/100ml (150 µg Pb/L) "does***		

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		not protect women and especially pregnant women properly" and called for revised exposure limit values for lead and its compounds while ensuring equal protection for all workers regardless of gender.		
Recital 7c				
17c		***(7c) This Directive respects the fundamental rights recognised in the Charter of Fundamental Rights of the European Union, in particular the prohibition of discrimination on the ground of sex and the right to fair and just working conditions provided for, respectively, in Articles 21 and 31 thereof. Moreover, it complies with Principle No 10 of the European Pillar of Social Rights, according to which workers have the right to a healthy, safe and well-adapted work environment. The right of workers to the protection of health and safety at work includes the right to protection from the effects of lead and its inorganic compounds on future generations, such as the***		

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		negative impacts on the reproductive capacity of men and women, as well as on foetal development. Therefore, the Biological Guidance Value for female workers of childbearing age should be assessed by the Commission in a forthcoming revision and established as a binding BLV as close to the reference values of the general population not occupationally exposed to lead in accordance with Article 18a, paragraph 7b of Directive 2004/37/EC. Such a BLV is intended to foster the full participation of female workers of childbearing age in economic sectors targeted by the European Green Deal, such as the production of sustainable and circular batteries, in support of the Union's energy transition.		
Recital 7a				
17d			**(7a) It may be difficult to comply with the biological limit value of 15 µg Pb/100 ml blood. This difficulty is due to the time needed to implement risk**	

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			management measures and costly adaptation of production processes, especially for companies operating in the sector of primary lead production. Therefore, a transitional value of 35 µg Pb/100 ml blood should apply until 31 December 2028.	
Recital 8				
18	(8) Moreover, to strengthen the health surveillance of workers exposed to lead and its inorganic compounds and thus contribute to the prevention and protection measures to be undertaken by the employer, it is necessary to amend the existing requirements that apply when workers are exposed to certain levels of lead and its inorganic compounds. To that end, detailed medical surveillance should be required when exposure to lead and its inorganic compounds exceeds 0.015 mg/m^3 in air (50% of current OEL) or 9 µg/100ml blood (approx. 60% of the current BLV).		(8) Moreover, to strengthen the health surveillance of workers exposed to lead and its inorganic compounds and thus contribute to the prevention and protection measures to be undertaken by the employer, it is necessary to amend the existing requirements that apply when workers are exposed to certain levels of lead and its inorganic compounds. To that end, detailed medical surveillance should be required when exposure to lead and its inorganic compounds exceeds ~~0.015~~**0,015** mg/m^3 in air (50% of ~~current OEL~~**occupational exposure limit value**) or 9 ~~µg/100ml~~**µg Pb/100 ml** blood (approx. 60% of the ~~current~~	

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			~~BLV~~**biological limit value**).	
Recital 8a				
18a		***(8a) Workers who have been occupationally exposed to lead over a number of years may have accumulated blood-lead levels well above the revised BLV. In the opinion of Committee for Risk Assessment, adverse health effects can already be observed at blood-lead levels that fall within the current BLV of 70 µg Pb/100ml. Employers should move such workers to other tasks in the workplace to ensure the fastest possible decrease in such workers' blood-lead levels. If this is not possible, workers with blood-lead levels between 15-30 µg Pb/100ml could be allowed continue performing tasks that involves exposure to lead, provided that a decline in their blood-lead level can be established. Such workers should be subject to enhanced and continued medical surveillance to ensure a downward trend in their blood-lead level. The Commission should, after consulting the ACSH***		

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		and the social partners, develop guidelines and recommendations concerning workers with historical exposure, as well as practical implementation by the Member States to ensure that their social safety net for such workers is covering them, for example adequate compensation, support and reskilling of workers who have been occupationally exposed to lead over a number of years.		
Recital 8a				
18b			**(8a) Lead accumulates in the bones and is released slowly from there into the circulatory system. Blood lead levels may thus remain high long after exposure to lead has been reduced. Therefore regular medical surveillance should be carried out for workers whose blood levels exceed the biological limit value in force due to exposure which occurred before [the date of transposition of this Directive]. If a declining trend towards the limit value in force is established, these workers may**	

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			be allowed to continue working with tasks that involve exposure to lead.	
Recital 9				
19	(9) Specific measures should be put in place with regard to risk management, including specific health surveillance that should take into consideration the circumstances of individual workers. Under the general requirements of Directive 2004/37/EC, employers are obliged to ensure the substitution of the substance when technically possible, the use of closed systems, or the reduction of exposure to as low as technically possible. In addition, as suggested in the opinion of the Advisory Committee on Safety and Health at Work[1], the blood level of lead and its inorganic compounds in women of childbearing age should not exceed the reference values of the general population not occupationally exposed to lead and its inorganic compounds in the respective Member State. The Committee for	(9) Specific measures should be put in place with regard to risk management, including ***hygiene measures, the use of personal protective equipment and*** specific health surveillance that should take into consideration the circumstances of individual workers. ***Since lead is a non-threshold reprotoxic substance, preventive medical surveillance should be one of the most important protection measures for lead-exposed workers, in addition to technical preventive measures to be taken by the employer.*** Under the general requirements of Directive 2004/37/EC, employers are obliged to ensure the substitution of the substance when technically possible, the use of closed systems, or the reduction of exposure to as low as technically possible. In addition, as suggested in the opinion of the Advisory	(9) Specific measures should be put in place with regard to risk management, including specific health surveillance that should take into consideration the circumstances of individual workers. Under the general requirements of– Directive 2004/37/EC, employers are obliged to ensure the substitution of the substance when technically possible, the use of closed systems, or the reduction of exposure to as low as technically possible. ~~In addition, as suggested in the opinion of the Advisory Committee on Safety and Health at Work[1], the blood level of lead and its inorganic compounds in women of childbearing age should not exceed the reference values of the general population not occupationally exposed to lead and its inorganic compounds in the respective Member State. The Committee for~~	

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	Risk Assessment (RAC) of the European Chemicals Agency (ECHA), established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[2], advised the use of a biological guidance value (BGV) as there was insufficient scientific evidence to set a BLV for women of childbearing age. When national reference levels are not available, blood levels of lead and its inorganic compounds in women of childbearing age should not exceed the BGV of 4.5 µg/100ml, as recommended by the opinion of the RAC[3]. The BGV is an indicator of exposure but not of identifiable adverse health effects. Therefore, it acts as a sentinel marker to alert employers on the need to pay specific attention to this specific potential risk and to introduce measures to ensure that any exposure to lead and its inorganic compounds does not result in adverse developmental health effects in the foetus or offspring of female workers. _____ 1. ACSH opinion on lead (2021). https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-	Committee on Safety and Health at Work[~~1~~ 90], the blood level of lead and its inorganic compounds in women of childbearing age should not exceed the reference values of the general population not occupationally exposed to lead and its inorganic compounds in the respective Member State. The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[~~2~~ 91], advised the use of a biological guidance value (BGV) as there was insufficient scientific evidence to set a BLV for women of childbearing age. When national reference levels are not available, blood levels of lead and its inorganic compounds in women of childbearing age should not exceed the BGV of 4.5 µg/100ml, as recommended by the opinion of the RAC[~~3~~ 92]. ***Due to a continuous decline in environmental lead exposure levels, this value should be revisited every five years***. The BGV is an indicator of exposure but not of identifiable adverse health effects. Therefore, it acts as	~~Risk Assessment (RAC) of the European Chemicals Agency (ECHA), established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[2], advised the use of a biological guidance value (BGV) as there was insufficient scientific evidence to set a BLV for women of childbearing age. When national reference levels are not available, blood levels of lead and its inorganic compounds in women of childbearing age should not exceed the BGV of 4.5 µg/100ml, as recommended by the opinion of the RAC[3]. The BGV is an indicator of exposure but not of identifiable adverse health effects. Therefore, it acts as a sentinel marker to alert employers on the need to pay specific attention to this specific potential risk and to introduce measures to ensure that any exposure to lead and its inorganic compounds does not result in adverse developmental health effects in the foetus or offspring of female workers.~~ _____ ~~1. ACSH opinion on lead (2021). https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-~~	

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	4c4588bd6541/library/60b206e1-ee10-40c2-9540-fb6510c11a0c/details 2. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.) 3. On the evaluation of the occupational exposure limits for lead and its compounds, delivered on 11 June 2020. (See section 8.2.4. of the annex to the opinion). https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037	a sentinel marker to alert employers on the need to pay specific attention to this specific potential risk and to introduce measures to ensure that any exposure to lead and its inorganic compounds does not result in adverse developmental health effects in the foetus or offspring of female workers. ***[90] ACSH opinion on lead (2021). https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/60b206e1-ee10-40c2-9540-fb6510c11a0c/details*** ***[91] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives***	~~4c4588bd6541/library/60b206e1-ee10-40c2-9540-fb6510c11a0c/details~~ ~~2. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)~~ ~~3. On the evaluation of the occupational exposure limits for lead and its compounds, delivered on 11 June 2020. (See section 8.2.4. of the annex to the opinion).~~ ~~https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037~~	

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		91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.) ***[92] On the evaluation of the occupational exposure limits for lead and its compounds, delivered on 11 June 2020. (See section 8.2.4. of the annex to the opinion). https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037*** ~~*1. ACSH opinion on lead (2021). https://circabc.europa.eu/ui/group/eb9293be-4563-4f19-89cf-4e4588bd6541/library/60b206e1-ee10-40e2-9540-fb6510e11a0e/details*~~ ~~*2. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)*~~ ~~*3. On the evaluation of the occupational exposure limits for lead and its compounds, delivered on 11 June 2020. (See section 8.2.4. of the annex to the opinion). https://echa.europa.eu/documents/10162/e*~~		

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		~~d7a37e1-1641-b147-aaac-fce4e3014037~~		
Recital 9a				
19a		***(9a) Some of the substances covered by this Directive, such as lead, are deemed necessary for the restoration of cultural heritage or certain cultural activities. For these substances and only when no suitable alternative exists, the Commission should assess the socio-economic benefits derived from the use of such substances against the risk posed to workers in these specific sectors or these activities. Based on this assessment and in consultation with the social partners, the Commission should consider targeted and limited exemptions for the cultural sector and heritage-related activities to existing OELs and BLVs.***		
Recital 9b				
19b		***(9b) Union-wide data from work-related health problems due to lead exposure are often lacking,***		

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		unreliable or insufficient. The Commission should develop guidelines and recommendations for data collection by the Member States to improve the reporting and exposures registries.		
Recital 9c				
19c		***(9c) There is a need for in-depth knowledge on the long-term effect of lead and its inorganic compounds. 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 of Directive 2004/37/EC, as well as the information and training requirements provided for in Articles 11 and 12 and hygiene and individual protection measures set out in Article 10 of that Directive take into consideration the vulnerable situation of women in childbearing age.***		
Recital 9a				

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19d			**(9a) In addition, the opinion of the Advisory Committee on Safety and Health at Work[1] suggested that the blood level of lead in women of childbearing age should not exceed the reference values of the general population not occupationally exposed to lead and its inorganic compounds in the respective Member State. The Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[2], advised the use of a biological guidance value as there was insufficient scientific evidence to set a biological limit value for women of childbearing age. In its opinion[3], RAC recommended that when national reference levels are not available, blood levels of lead in women of childbearing age should not exceed 4,5 µg Pb/100 ml blood because the biological limit value for lead does not protect the foetus or offspring of women of childbearing age.**	

	Commission Proposal	EP Mandate	9619/23 Council Mandate	Draft Agreement
			_____ **1. ACSH opinion on lead (2021). https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/60b206e1-ee10-40c2-9540-fb6510c11a0c/details** **2. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1.)** **3. On the evaluation of the occupational exposure limits for lead and its compounds, delivered on 11 June 2020. (See section 8.2.4. of the annex to the opinion). https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037** Mostly taken from recital 9	
Recital 9b				
19e			**(9b) Therefore, medical surveillance should be carried out for women of childbearing age whose blood lead levels**	

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			exceed 4,5 µg Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead, if such value exists. The value 4,5 µg Pb/100 ml blood is an indicator of exposure but not of identifiable adverse health effects. Therefore, it acts as a sentinel marker to alert employers on the need to pay specific attention to this specific potential risk and to introduce measures to ensure that any exposure to lead and its inorganic compounds does not result in adverse developmental health effects in the foetus or offspring of female workers. This provision complements the existing obligations regarding risks assessment, information and training, which are important tools to minimise risk. Partly taken from recital 9	
Recital 9c				
19f			**(9c) In order to assist Member States, the Commission should prepare Union guidelines on**	

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			health surveillance including biological monitoring, which should also focus on the implementation of provisions regarding blood lead level, taking into account the slow removal of lead from the body. Those Union guidelines should also focus on the implementation of provisions regarding blood lead level for women of childbearing age to protect the foetus and offspring.	
Recital 9d				
19g			**(9d) It is essential that the protection of the safety and health of the foetus or offspring of female workers does not lead to the unfavourable treatment of women on the labour market nor work to the detriment of Union legislation concerning equal treatment for men and women.**	
Recital 10				
20	(10) Diisocyanates are skin and respiratory sensitisers (asthmagens)		(10) Diisocyanates are skin and respiratory sensitisers (asthmagens)	

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	that can have harmful respiratory health effects such as occupational asthma, isocyanate sensitisation and bronchial hyper-responsiveness, as well as dermal occupational disease. They are considered as hazardous chemical agents within the meaning of Article 2, point (b), of Directive 98/24/EC and thus fall within its scope. Currently there is no binding occupational exposure limit value or short-term exposure limit value for diisocyanates at Union level.		that can have harmful respiratory health effects such as occupational asthma, isocyanate sensitisation and bronchial hyper-responsiveness, as well as dermal occupational disease. ~~They~~**Skin exposure may possibly also result in systemic immunological effects like sensitisation of the respiratory tract. Diisocyanates** are considered as hazardous chemical agents within the meaning of Article 2, point (b), of Directive 98/24/EC and thus fall within its scope. Currently there is no binding occupational exposure limit value or short-term exposure limit value for diisocyanates at Union level.	
Recital 10a				
20a			**(10a) To ensure a more comprehensive level of protection, it is also necessary to consider absorption pathways other than inhalation for diisocyanates. This could include possible health effects following skin exposure, including systemic immunological effects. Further**	

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			notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008 of the European Parliament and of the Council[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 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 11				
21	(11) It is not scientifically possible to identify levels below which exposure to diisocyanates would not lead to adverse health effects. Instead, an exposure-risk relationship can be established, facilitating the setting of an occupational exposure limit by taking into account an acceptable level of excess risk. As a consequence, limit values for diisocyanates should be established in order to reduce the risk by lowering exposure levels. It is therefore possible, based on the available information, including		(11) It is not scientifically possible to identify levels below which exposure to diisocyanates would not lead to adverse health effects. Instead, an exposure-risk relationship can be established, facilitating the setting of an occupational exposure limit by taking into account ~~an acceptable~~ level of excess risk. As a consequence, limit values for **all** diisocyanates should be established in order to reduce the risk by lowering exposure levels. It is therefore possible, based on the available information, including	

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	scientific and technical data, to set a long-term and short-term limit value for that group of chemical agents.		scientific and technical data, to set a long-term and short-term limit value for that group of chemical agents.	
Recital 12				
22	(12) Diisocyanates can be absorbed through the skin and exposure to diisocyanates at the place of work may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish an occupational exposure limit of 6 µg/m³ and a short-term exposure limit of 12 µg/m³ for this group of chemical agents and to assign a skin, dermal and respiratory sensitisation notation to it.	(12) Diisocyanates can be absorbed through the skin and exposure to diisocyanates at the place of work may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish an occupational exposure limit of 6 ~~µg/m~~***µg NCO/m***³ and a short-term exposure limit of 12 ~~µg/m~~***µg NCO/m***³ for this group of chemical agents and to assign a skin, dermal and respiratory sensitisation notation to it.	(12) ~~Diisocyanates can be absorbed through the skin and~~**It is therefore appropriate to establish an occupational** exposure ~~to diisocyanates at the place of work may also result in dermal sensitisation and sensitisation of the~~**limit of 6 µg NCO/m³ and a short-term exposure limit of 12 µg NCO/m³ for all diisocyanates and to assign a skin, dermal and** respiratory ~~tract. It is therefore appropriate to establish an occupational exposure limit of 6 µg/m³ and a short-term exposure limit of 12 µg/m³ for this group of chemical agents and to assign a skin, dermal and~~**sensitisation notation to it, where NCO refers to isocyanate functional groups of the diisocyanate compounds. In line with Articles 6(3) and 10 of Directive 98/24/EC, health**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			surveillance is important to identify early signs and symptoms of respiratory sensitisation ~~notation to it~~..	
Recital 13				
23	(13) It may be difficult to comply with an occupational exposure limit equal to 6 µg/m³ for diisocyanates, accompanied by an associated short-term exposure limit equal to 12 µg/m³. This difficulty is due to technical measurement feasibility issues and the time needed to implement risk management measures in particular in downstream sectors involving activities such as applications of paints, work with lead metal, demolition, repair and scrap management, other waste management and soil remediation. Therefore, a transitional value of 10 µg/m³ with an associated short-term exposure limit equal to 20 µg/m³ should apply until 31 December 2028.	(13) It may be difficult to comply with an occupational exposure limit equal to 6 ~~µg/m~~***µg NCO/m***³ for diisocyanates, accompanied by an associated short-term exposure limit equal to 12 ~~µg/m~~***µg NCO/m***³. This difficulty is due to technical measurement feasibility issues and the time needed to implement risk management measures in particular in downstream sectors involving activities such as applications of paints, work with lead metal, demolition, repair and scrap management, other waste management and soil remediation. Therefore, a transitional value of 10 ~~µg/m~~***µg NCO/m***³ with an associated short-term exposure limit equal to 20 ~~µg/m~~***µg NCO/m***³ should apply until 31 December 2028.	(13) It may be difficult to comply with an occupational exposure limit equal to 6 ~~µg/m~~**µg NCO/m**³ for diisocyanates, accompanied by an associated short-term exposure limit equal to 12 ~~µg/m~~**µg NCO/m**³. This difficulty is due to technical measurement feasibility issues and the time needed to implement risk management measures in particular in downstream sectors ~~involving activities such as applications of paints, work with lead metal, demolition, repair and scrap management, other waste management and soil remediation~~. Therefore, a transitional value of 10 ~~µg/m~~**µg NCO/m**³ with an associated short-term exposure limit equal to 20 ~~µg/m~~**µg NCO/m**³ should apply until 31 December 2028.	
Recital 14				

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24	(14) The Commission has consulted the Committee for Risk Assessment) which provided opinions on both substances. The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty. It has also consulted the Advisory Committee on Safety and Health, which adopted opinions regarding the revision of the limit values for lead and its inorganic compounds[1] and establishment of an occupational limit value for diisocyanates[2], with recommendations for appropriate notations. _____ 1. See footnote 8. 2. ACSH opinion on diisocyanates (2021) https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/0d11d394-b1e8-4e1a-a962-5ad60f4ab2ae/details	(14) The Commission has consulted the Committee for Risk Assessment) which provided opinions on both substances. The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty. It has also consulted the Advisory Committee on Safety and Health ***at Work***, which adopted opinions regarding the revision of the limit values for lead and its inorganic compounds~~1~~***93*** and establishment of an occupational limit value for diisocyanates~~2~~***94***, with recommendations for appropriate notations***, and a review of the limit values for diisocyanates starting in 2029***. ***Therefore, the Commission should launch the process of evaluating the need to modify the binding limit values for diisocyanates and should, after consulting the ACSH, where appropriate, propose necessary amendments to that group of substances, and taking into account the number of cases on occupational asthma reported by the Member States to***	(14) The Commission has consulted the Committee for Risk Assessment~~)~~ which provided opinions on both substances. The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty. It has also consulted the Advisory Committee on Safety and Health **at Work**, which adopted opinions regarding the revision of the limit values for lead and its inorganic compounds[1] and establishment of ~~an~~ occupational limit ~~value~~**values** for diisocyanates[2], with recommendations for appropriate notations **and a review of the limit values for diisocyanates starting in 2029**. _____ 1. See footnote ~~8~~**9**. 2. ACSH opinion on diisocyanates (2021) https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/0d11d394-b1e8-4e1a-a962-5ad60f4ab2ae/details	

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		the Commission. ***[93] See footnote 8.*** ***[94] ACSH opinion on diisocyanates (2021) https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/0d11d394-b1e8-4e1a-a962-5ad60f4ab2ae/details*** ~~*1. See footnote 8.*~~ ~~*2. ACSH opinion on diisocyanates (2021) https://circabc.europa.eu/ui/group/cb9293be-4563-4f19-89cf-4c4588bd6541/library/0d11d394-b1e8-4e1a-a962-5ad60f4ab2ae/details*~~		
Recital 14a				
24a		***(14a) 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. Exposure to cobalt and cobalt compounds at workplaces may result in dermal sensitisation and the sensitisation of the respiratory tract. It is***		

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		therefore appropriate, on the basis of the available information, including scientific and technical data, to establish limit values urgently for both the inhalable and respirable fractions of cobalt and of cobalt compounds in Directive 2004/37/EC.		
Recital 14b				
24b		***(14b) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. By 1 January 2030, the limit value for benzene set out in Annex III to Directive 2004/37/EC should be revised in light of more recent scientific data, after consulting the ACSH. It is appropriate to keep the skin notation. Following the opinion of RAC, the ACSH also agreed about the usefulness of the biomonitoring for benzene. Those matters should be taken into account when developing***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		guidance on the practical use of biomonitoring.		
Recital 15				
25	(15) The limit values established in this Directive should be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006.		(15) **It is crucial to keep** the limit values established in this Directive ~~should be kept~~ under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006.	
Recital 15a				
25a		***(15a) The Occupational Exposure Limit Value and the Biological Limit Values, including the limit value for historical exposure and the guidance value for female workers of childbearing age on lead, should be kept under regular scrutiny and strictly reviewed at least every five years, after the entry into force of this directive. Such a review should be done on the basis of advances in knowledge and technologies and up-to-date scientific data, in order to address the negative impacts on the reproductive capacity of***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		female workers of childbearing age as well as on foetal development and to ensure equal protection for all workers regardless of their gender. Such a review should also take into account the classification of lead as a non-threshold reprotoxic.		
Recital 15b				
25b		***(15b) After the introduction of the amendments to Annex III to Directive 2004/37/EC provided for in this Directive, further limit values for additional substances or groups of substances and processes should be introduced by the end of 2024. Between 50 and 70 substances or groups 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 [one year after the entry into force of this Directive], update its action plan to achieve***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		occupational exposure limits for at least 5 additional substances or groups of substances or process-generated substances. The additional substances or groups of substances referred to in Annex III to Directive 2004/37/EC should include but not be limited to substances and processes such as lithium and lithium compounds, methyl hydrazine, 1,3-propanesultone, welding fumes and leather dust.		
Recital 15c				
25c		***(15c) Substances and mixtures with endocrine disrupting properties pose a concern to public health. It has been proven that endocrine disruption can lead to certain disorders in humans, such as birth defects, developmental, reproductive or neurodevelopmental disorders, cancer, diabetes and obesity. The Commission communication of 14 October 2020 entitled 'Chemicals strategy for sustainability. Towards a toxic-free environment' highlighted the need***		

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		to establish a legally binding hazard identification of endocrine disruptors and to protect workers from those substances. Following the adoption of the Commission Delegated Regulation (EU) 2023/707[1a] and the introduction of a new hazard class for endocrine disruptors, such substances should be covered by Union health and safety law. It is therefore necessary to consider extending the scope of Directive 2004/37/EC to endocrine disruptors, which have the ability to interfere with the hormonal system and can therefore induce adverse health effects. ***[1a] Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7).***		
Recital 15d				
25d				

	Commission Proposal	EP Mandate	9619/23 Council Mandate	Draft Agreement
		(15d) To ensure a comprehensive level of protection, it is necessary to consider the effects of combined exposure to multiple substances. 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 15e				
25e		***(15e) The World Health Organization has classified the occupational exposure of firefighters as carcinogenic (Group 1). Occupational exposure of firefighters includes a variety of hazards resulting from fires and non-fire events. Firefighters can be exposed to combustion products from fires, building materials, chemicals in***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		firefighting foams, flame retardants and diesel exhaust. The uptake of fire effluents or other chemicals can occur by inhalation and dermal absorption and possibly via ingestion. Such workers should therefore be better protected from such exposure.		
Recital 15f				
25f		***(15f) Union action, such as the European Green Deal launched in the Commission communication of 11 December 2019 and the Critical Raw Material initiative launched in the Commission communication of 16 March 2023, entitled 'A secure and sustainable supply of critical raw materials in support of the twin transition', promote sustainable development, such as for example the batteries sector which is one of the several sectors of strategic importance to reach the objectives of Regulation (EU) 2021/1119. This requires a balance between environmental, economic, and social considerations. By enacting binding occupational exposure***		

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		limits of carcinogens, mutagens and reprotoxic substances, workers are better protected from harm and can continue to work as safely as possible in industries that produce critical raw materials, such as lead, stimulating the circular economy and maintaining and enhancing the international strategic autonomy in raw materials, which are all priorities of the Union. Protecting workers from exposure to hazardous substances also contributes to the objectives of "Europe's Beating Cancer Plan", set out in the Commission communication of 3 February 2021. This promotes a just, green and digital transition in which workers' health and a high level of protection go hand in hand with the Union's economic and environmental goals. Because of the harmful properties of lead and its inorganic compounds, relocation of lead-processing companies to third countries with less stringent occupational safety and health regulations needs to be avoided at all times, while offering the highest level of protection for		

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		workers in the Union.		
Recital 15g				
25g		***(15g) Due to unpredictable exposure to certain substances, a mix of substances or constraints in the organisation of work, some occupations should be considered to be carcinogenic per se. For some occupations it is difficult to predict and prepare for the extent to which workers will be exposed to substances or mixes of substances. It is to be expected that the World Health Organization's list of carcinogenic hazards will be expanded in accordance with the increasing amount of data and the progress of medical and scientific research, which highlight the carcinogenic nature of some occupations. Therefore, the Commission should develop a definition of carcinogenic occupations with the purpose of supporting employers in identifying at-risk professions, and to facilitate the implementation of adequate***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		protective measures and training pursuant to Directives 98/24/EC and 2004/37/EC.		
Recital 15h				
25h		***(15h) The circular economy and the waste collecting, sorting and recovery sectors are growing fast to meet the objectives of the European Green Deal, in order to ensure the sustainability of European industry and to ensure greater strategic autonomy to the Union. However, those positive developments raise many occupational health and safety issues for workers in that industry, who, by the very nature of their activity, are likely to be disproportionately exposed to harmful substances. Exposure to lead, mercury and other hazardous metals in waste recycling facilities is for example already a reality for many such workers. Ambitious protective measures, adequate prevention policies, as well as good quality working conditions are necessary to reduce the risks of exposure to***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		hazardous substances and to ensure a high level of protection.		
Recital 15i				
25i		***(15i) Informal workers are present in the waste collecting, sorting and recovery sectors. A high exposure to risks, including harmful substances, combined with a low level of social protection place most informal economy workers in a very vulnerable situation. Preventive measures, in the form of occupational health and safety management systems and a general safety culture, to reduce risks at work often do not reach the informal economy. The protective measures of this Directive should apply equally to all workers. To this end, full enforcement of this Directive, including by way of labour inspections, is necessary in order to ensure safe working conditions and environments as well as equal treatment of workers across sectors.***		

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Recital 16				
26	(16) The objective of this Directive, namely to protect workers against risks to their health and safety arising from or likely to arise from exposure to chemical agents and reprotoxic substances at work, including the prevention of such risks, cannot be sufficiently achieved by the Member States acting alone. Rather, by reason of its scale and effects, it can be better achieved at Union level. Therefore, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.		(16) The objective of this Directive, namely to protect workers against risks to their health and safety arising from or likely to arise from exposure to chemical agents and reprotoxic substances at work, including the prevention of such risks, cannot be sufficiently achieved by the Member States acting alone. Rather, by reason of its scale and effects, it can be better achieved at Union level. Therefore, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective.	
Recital 17				
27	(17) Since this Directive concerns the protection of the health and safety of workers at the place of work, it should be transposed within two years of the date of its		(17) Since this Directive concerns the protection of the health and safety of workers at the place of work, it should be transposed within two years of the date of its	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	entry into force.		entry into force.	
Recital 18				
28	(18) Directives 98/24/EC and 2004/37/EC should therefore be amended accordingly.		(18) Directives 98/24/EC and 2004/37/EC should therefore be amended accordingly.	
Formula				
29	HAVE ADOPTED THIS DIRECTIVE:		HAVE ADOPTED THIS DIRECTIVE:	
Article 1				
30	Article 1		Article 1	
Article 1, first paragraph				
31	Directive 98/24/EC is amended as follows:		Directive 98/24/EC is amended as follows:	
Article 1, first paragraph, point (-1)				
31a		***(-1) in Article 12, the following paragraph is added:***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 1, first paragraph, point (-1a)				
31b		***'2a. No later than 31 December 2029, the Commission shall launch a revision process for the occupational exposure limit and the short-term occupational exposure limit values for diisocyanates, taking especially into account the evaluation of the REACH Regulation and any relevant data available and shall, where appropriate, submit necessary amendments to the group of substances set out in Annex I without delay.';***		
Article 1, first paragraph, point (1)				
32	(1) Annex I is amended in accordance with Annex I to this Directive;		(1) Annex I is amended in accordance with Annex I to this Directive;	
Article 1, first paragraph, point (2)				
33	(2) in Annex II, points 1, 1.1, 1.2 and 1.3 are deleted.		(2) in Annex II, points 1, 1.1, 1.2 and 1.3 are deleted.	

	Commission Proposal	EP Mandate	9619/23 Council Mandate	Draft Agreement
Article 2				
34	Article 2		Article 2	
Article 2, first paragraph -a				
34a		***Directive 2004/37/EC is amended as follows:***	**Directive 2004/37/EC is amended as follows:**	
Article 2, second paragraph				
34b		***(1) in Article 2(1), point (b) is replaced by the following:***		
Article 2, third paragraph				
34c		***"***(b) 'mutagen' means: ***(i)*** a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008; ***(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Annex;"		
Article 2, fourth paragraph				
34d		***(2) in Article 2(1), point (ba) is replaced by the following:***		
Article 2, fifth paragraph				
34e		***"***(ba) 'reprotoxic substance' means***:*** ***(i)*** a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008; ***(ii) a substance, mixture or process referred to in Annex I to this Directive as well as a substance or mixture released by a process referred to in that Annex;"***		
Article 2, sixth paragraph				
34f		***(3) in Article 2(1), the following point is added:***		

	Commission Proposal	EP Mandate	9619/23 Council Mandate	Draft Agreement
Article 2, seventh paragraph				
34g		***"(ea) 'hazardous medicinal products' or 'HMP' means medicinal products that contain one or more substances that meet the criteria for classification as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008.";***		
Article 2, eighth paragraph				
34h		***(4) in Article 5, paragraph 4 is replaced by the following:***		
Article 2, ninth paragraph				
34i		***"***4. Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III. ***Biological levels shall not exceed the biological limit value for a carcinogen, mutagen or a reprotoxic substance as set out in Annex IIIa."***		

	Commission Proposal	EP Mandate	9619/23 Council Mandate	Draft Agreement
Article 2, tenth paragraph				
34j		***(5) in Article 5, the following paragraph is added:***		
Article 2, eleventh paragraph				
34k		***"4a. 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 of such substances in accordance with Union guidelines, pursuant to Article 18a, paragraph 7a.";***		
Article 2, twelfth paragraph				
34l		***(6) in Article 18a, paragraph 7 is replaced by the following:***		
Article 2, thirteenth paragraph				
34m		***"***No later than 31 December ~~2024~~***2023***, the Commission shall***, after consulting the ACSH***, taking		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		into account ***the RAC's 2018 opinion and*** the latest developments in scientific knowledge, ~~*and after*~~***where*** appropriate~~ *consultation of relevant stakeholders, propose, where appropriate,*~~ ***, submit a legislative proposal to introduce*** a limit value for cobalt and inorganic cobalt compounds.***";***		
Article 2, fourteenth paragraph				
34n		***(7) in Article 18a, the following paragraph is added:***		
Article 2, fifteenth paragraph				
34o		***"By ... [one year after the date of entry into force of this amending Directive], the Commission shall, taking into account the latest developments in scientific knowledge and the opinion of the Committee for Risk Assessment of the European Chemicals Agency established by Regulation (EC) No 1907/2006, and after appropriate consultation of relevant stakeholders, prepare Union***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		guidelines on how the implementation of the limit values referred to in Article 5(4a) 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 shall be disseminated in all Member States by the relevant competent authorities.";		
Article 2, sixteenth paragraph				
34p		***(8) in Article 18a, the following paragraph is added:***		
Article 2, seventeenth paragraph				
34q		***"By ... [12 months after the date of entry into force of this amending directive], the Commission shall review the implementation of this Directive. In the context of that review, it shall consider whether further amendments to this Directive are appropriate, shall assess the feasibility of including endocrine disrupters within the scope of this Directive and shall, where***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		appropriate, submit to the European Parliament and to the Council a legislative proposal.";		
Article 2, eighteenth paragraph				
34r		***(9) in Article 18a, the following paragraph is added:***		
Article 2, nineteenth paragraph				
34s		***'By... [five years after the date of entry into force of this amending directive] and every five years thereafter, the Commission shall review the Occupational Exposure Limit Value and the Biological Limit Values including the limit value for historical exposure and the guidance value for female workers of childbearing age, laid down in Annex III and IIIa, taking into account the negative impacts on the reproductive capacity of female workers of childbearing age as well as on foetal development in order to ensure equal protection for all workers regardless of their gender as well as taking into account up-***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		to-date scientific data and the classification of lead as a non-threshold reprotoxic.'		
Article 2, twentieth paragraph				
34t		***(10) in Article 18a, the following paragraph is added:***		
Article 2, twenty-first paragraph				
34u		***"By ... [twelve months after the date of entry into force of this amending Directive], the Commission shall, after consulting the Advisory Committee for Safety and Health at Work (ACSH), develop a definition of 'carcinogenic occupations' and assess the appropriateness to include such occupations in the scope of this Directive.";***		
Article 2, twenty-second paragraph				
34v		***(11) in Article 18a, the following paragraph is added:***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 2, twenty-third paragraph				
34w		***"By ... [twelve months after the date of entry into force of this amending Directive], the Commission shall, after consulting the ACSH, develop guidelines as regards historical occupational exposure to lead with a view to increasing the protection and reduction of the exposure of workers whose blood-lead levels are above the biological limit value as well as to further protect female workers of childbearing age. Those guidelines shall be published on the EU-OSHA website and shall be disseminated in all Member States by the relevant competent authorities."***		
Article 2, twenty-fourth paragraph				
34x		***(12) in Article 18a, the following paragraph is added:***		
Article 2, twenty-fifth paragraph				
34y		***"By [one year after the entry into***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		force of this Directive], the Commission shall, after consulting the ACSH and taking into account existing recommendations made by relevant agencies, stakeholders and the World Health Organization with regard to priority carcinogens, mutagens and reprotoxic substances for which limit values are needed, revise its action plan to achieve occupational exposure limits values for substances, or groups of substances or process-generated substances additional to those referred to in this Directive. This shall in particular include lithium and lithium compounds, methyl hydrazine, 1,3-propanesultone, welding fumes and leather dust. By [two years after the entry into force of this Directive], the Commission shall, taking into account that revised action plan to achieve limit values for additional substances or group of substances or process-generated substances, the latest developments in scientific knowledge, and after consulting the ACSH, submit to the		

	Commission Proposal	EP Mandate	9619/23 Council Mandate	Draft Agreement
		European Parliament and the Council, where appropriate, a legislative proposal.";		
Article 2, twenty-sixth paragraph				
34z		***(13) in Article 18a, the following paragraph is added:***		
Article 2, twenty-seventh paragraph				
34aa		***"By ... [twelve months after the date of entry into force of this amending Directive], the Commission shall, in consultation with social partners, consider targeted and limited exemptions for cultural and heritage-related work activities to existing Occupational Exposure Limit Values and Biological Limit Values, and take appropriate action."***		
Article 2, twenty-eighth paragraph				
34ab		***(14) in Article 18a, the following paragraph is added:***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 2, twenty-ninth paragraph				
34ac		***"By 1 January 2028, the Commission shall, taking into account the RAC's 2018 opinion and the latest developments in scientific knowledge, assess the feasibility of a further reduction of the limit value for benzene and shall, by 1 January 2030, where appropriate, submit to the European Parliament and the Council the necessary legislative amendments to this Directive.";***		
Article 2, second paragraph				
34ad			**(1) the following subparagraph is added in Article 18a:**	
Article 2, third paragraph				
34ae			**'No later than [one year before the transposition deadline] the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines for health surveillance including biological**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			monitoring. Those guidelines shall include advice on the implementation of provisions regarding blood lead level, taking into account the slow removal of lead from the body and the special protection of women of childbearing age.'	
Article 2, first paragraph				
35	Annexes III and IIIa to Directive 2004/37/EC are amended in accordance with Annex II to this Directive.	Annexes ***I,*** III and IIIa to Directive 2004/37/EC are amended in accordance with Annex II to this Directive.	Annexes III and IIIa to Directive 2004/37/EC are amended in accordance with Annex II to this Directive.	
Article 3				
36	Article 3		Article 3	
Article 3, first paragraph				
37	Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years of the date of entry into force of this Directive at		Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years of the date of entry into force of this Directive at	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the latest. They shall immediately inform the Commission thereof.		the latest. They shall immediately inform the Commission thereof.	
Article 3, second paragraph				
38	When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.		When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.	
Article 3, third paragraph				
39	Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.		Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.	
Article 4				
40	Article 4		Article 4	
Article 4, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
41	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		This Directive shall enter into force on the twentieth day following that of its publication in the ***Official Journal of the European Union*** ~~Official Journal of the European Union~~.	
Article 5				
42	Article 5		Article 5	
Article 5, first paragraph				
43	This Directive is addressed to the Member States.		This Directive is addressed to the Member States.	
Formula				
44	Done at Brussels,		Done at Brussels,	
Formula				
45	For the European Parliament		For the European Parliament	
Formula				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
46	The President		The President	
Formula				
47	For the Council		For the Council	
Formula				
48	The President		The President	
Annex I				
49	Annex I			
Annex I, first paragraph				
50	Annex I to Directive 98/24/EC is replaced by the following:			
Annex I, first paragraph, amending provision, first paragraph				
51	‘ ANNEX I	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, second paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
52	LIST OF BINDING OCCUPATIONAL EXPOSURE LIMIT VALUES	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 1, Row 1				
53	Name of agent	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 1, Row 4				
54	Diisocyanates	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 2, Row 1				
55	EC No (1)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 2, Row 4				
56		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 3, Row 1				
57				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	CAS No (2)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 3, Row 4				
58		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 4, Row 1				
59	Limit values	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 1, Row 2				
60	8 hours (3)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 1, Row 3				
61	µg/m3 (5)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 4, Row 4				
62	6			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 2, Row 3				
63	Ppm (6)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 5, Row 4				
64		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 3, Row 3				
65	f/ml (7)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 6, Row 4				
66		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 4, Row 2				
67	Short-term (4)	Treated outside TTE	Treated outside TTE	Treated outside TTE

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, first paragraph, amending provision, Table 1, Column 4, Row 3				
68	µg/m3	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 7, Row 4				
69	12	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 5, Row 3				
70	ppm	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 8, Row 4				
71		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 9, Row 1				
72	Notation	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 9, Row 4				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
73	Skin (8) Dermal and respiratory sensitisation (9)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 10, Row 1				
74	Transitional measures	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, Table 1, Column 10, Row 4				
75	The limit value of 10 µg/m3 in relation to a reference period of eight hours and a short-term exposure limit value of 20 µg/m3 shall apply until 31 December 2028.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (1)				
76	(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.	Treated outside TTE	Treated outside TTE	Treated outside TTE

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex I, first paragraph, amending provision, numbered paragraph (2)				
77	(2) CAS No: Chemical Abstract Service Registry Number.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (3)				
78	(3) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (4)				
79	(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.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (5)				
80	(5) µg/m^3 = micrograms per cubic metre of air.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (6)				
81	(6) ppm = parts per million by			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	volume in air (ml/m3).	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (7)				
82	(7) f/ml = fibres per millilitre.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (8)				
83	(8) The substance can cause sensitisation of the skin.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (9)				
84	(9) The substance can cause sensitisation of the skin and of the respiratory tract.. ,	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex I, first paragraph, amending provision, numbered paragraph (9a)				
84a		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II				
85	Annex II			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Treated outside TTE	
Annex II, first paragraph				
86	Annexes III and IIIa to Directive 2004/37/EC are amended as follows:	Annexes ***I,*** III and IIIa to Directive 2004/37/EC are amended as follows:	Treated outside TTE	
Annex II, first paragraph a				
86a		***(-1) in Annex I, the title is amended as follows:***		
Annex II, second paragraph				
86b		***"***List of substances, preparations and processes (Article 2(a)(~~iii~~***ii), 2(b)(ii), 2(ba)(ii))";***		
Annex II, third paragraph				
86c		***(-1a) in Annex I, the following point is added:***		
Annex II, fourth paragraph				
86d				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		"8a. Work involving exposure to hazardous medicinal products.";		
Annex II, second paragraph				
87	(1) in Annex III, point A, the row related to inorganic lead and its compounds is replaced by the following:	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, first paragraph				
88	‘	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 1, Row 1				
89	Name of agent	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 1, Row 4				
90	Inorganic lead and its compounds	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 2, Row 1				
91				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	EC No (1)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 2, Row 4				
92		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 3, Row 1				
93	CAS No (2)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 3, Row 4				
94		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 4, Row 1				
95	Limit values	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 1, Row 2				
96	8 hours (3)			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 1, Row 3				
97	mg/m3 (5)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 4, Row 4				
98	0.03	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 2, Row 3				
99	Ppm (6)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 5, Row 4				
100		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 3, Row 3				
101	f/ml (7)	Treated outside TTE	Treated outside TTE	Treated outside TTE

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex II, second paragraph, amending provision, Table 2, Column 6, Row 4				
102		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 4, Row 2				
103	Short-term (4)	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 4, Row 3				
104	mg/m3	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 7, Row 4				
105		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 5, Row 3				
106	ppm	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 8, Row 4				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
107		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 6, Row 3				
108	f/ml	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 9, Row 4				
109		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 10, Row 1				
110	Notation	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 10, Row 4				
111		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 11, Row 1				
112	Transitional measures			

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, Table 2, Column 11, Row 4				
113		Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, numbered paragraph (1)				
114	(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.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, numbered paragraph (2)				
115	(2) CAS No: Chemical Abstract Service Registry Number.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, numbered paragraph (3)				
116	(3) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).	Treated outside TTE	Treated outside TTE	Treated outside TTE

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex II, second paragraph, amending provision, numbered paragraph (4)				
117	(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.	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, numbered paragraph (5)				
118	(5) mg/m3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, numbered paragraph (6)				
119	(6) ppm = parts per million by volume in air (ml/m3).	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, numbered paragraph (7)				
120	(7) f/ml = fibres per millilitre.; ,	Treated outside TTE	Treated outside TTE	Treated outside TTE
Annex II, second paragraph, amending provision, numbered paragraph (7a)				
120a		Treated outside TTE	Treated outside TTE	Treated outside TTE

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex II, third paragraph				
121	(2) Annex IIIa is replaced by the following:	(2) Annex IIIa is replaced by the following:	(2) Annex IIIa is replaced by the following:	
Annex II, third paragraph, amending provision, first paragraph				
122	‘ ANNEX IIIa	‘ ANNEX IIIa	‘ ANNEX IIIa	
Annex II, third paragraph, amending provision, second paragraph				
123	BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES	BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES	BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES	
Annex II, third paragraph, amending provision, third paragraph				
124	(Article 16(4))	(Article 16(4))	(Article 16(4))	
Annex II, third paragraph, amending provision, fourth paragraph				
125	Lead and its ionic compounds	Lead and its ~~*ionic*~~***inorganic*** compounds	**1.** Lead and its ~~ionic~~**inorganic** compounds	
Annex II, third paragraph, amending provision, fifth paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
126	Biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:	Biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:	**1.1.** Biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. ~~The binding biological limit value is:~~	
Annex II, third paragraph, amending provision, fifth paragraph a				
126a			**Until 31 December 2028, the binding biological limit value is:**	
Annex II, third paragraph, amending provision, seventh paragraph				
126b			**35 µg Pb/100 ml blood**	
Annex II, third paragraph, amending provision, eighth paragraph				
126c			**For workers whose blood lead level exceeds the biological limit value of 35 µg Pb/100 ml blood due to exposure which has occurred before [the date of transposition of this Directive], but is below 70 µg Pb/100 ml blood, medical surveillance is carried out on a regular basis. If a declining trend towards the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			limit value of 35 µg Pb/100 ml blood is established in those workers, […] those workers may be allowed to continue with work involving exposure to lead.	
Annex II, third paragraph, amending provision, ninth paragraph				
126d			**As of 1 January 2029, the binding biological limit value is:**	
Annex II, third paragraph, amending provision, fifth paragraph, first paragraph				
127	15 µg Pb/100 ml blood ([1])	15 µg Pb/100 ml blood ([1])	15 µg Pb/100 ml blood ~~([1])~~	
Annex II, third paragraph, amending provision, fifth paragraph, first paragraph, first paragraph				
127a			**For workers whose blood lead level exceeds the biological limit value of 15 µg Pb/100 ml blood due to exposure which has occurred before [the date of transposition of this Directive], but is below 35 µg Pb/100 ml blood, medical surveillance is carried out on a regular basis. If a declining trend towards the limit value of 15 µg Pb/100 ml blood is established in those**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			workers, those workers may be allowed to continue with work involving exposure to lead.	
Annex II, third paragraph, amending provision, fifth paragraph, first paragraph, second paragraph				
127b		***If the results of the medical surveillance reveal a blood-lead level of a worker greater than 30 µg Pb/100 ml blood, the employer and the authority responsible for the health surveillance of that worker shall ensure that the worker is no longer exposed to lead in accordance with the guidelines developed pursuant to Article 18a.***		
Annex II, third paragraph, amending provision, fifth paragraph, first paragraph, third paragraph				
127c		***If the results of the medical surveillance reveal a blood-lead level of a worker between 15-30 µg Pb/100 ml blood and if a declining trend towards the limit value in force is established, then that worker may continue working with tasks that involve exposure to lead.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Annex II, third paragraph, amending provision, fifth paragraph, first paragraph, fourth paragraph				
127d		***Specific measures, shall be put in place with regard to risk management, including specific and regular health surveillance, high standards for personal protective equipment and regular blood-lead checks. Under the general requirement of Directive 2004/37/EC, employers are obliged to ensure the substitution of the substances when technically possible, the use of closed systems, or the reduction of exposure to as low as technically possible.***		
Annex II, third paragraph, amending provision, sixth paragraph				
128	Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0,015 mg/m^3, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than 9 µg Pb/100 ml blood is measured in individual workers.	Medical surveillance is carried out ~~*if exposure to a concentration of lead in air is greater than 0,015 mg/m^3, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than 9 µg Pb/100 ml blood is measured in individual workers*~~***regularly for all workers exposed to lead and its inorganic compounds***.	**1.2.** Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0,015 mg/m^3, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than 9 µg Pb/100 ml blood is measured in individual workers. **Medical surveillance is also carried out for women of childbearing age whose blood lead levels exceed 4,5 µg Pb/100**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			ml blood or the national reference value of the general population not occupationally exposed to lead, if such value exists.'	
Annex II, third paragraph, amending provision, numbered paragraph (1)				
129	(1) It is recommended that the blood lead level in women of childbearing age does not exceed the reference values of the general population not occupationally exposed to lead in the respective EU Member State. When national reference levels are not available, it is recommended that blood lead levels in women of childbearing age do not exceed the Biological Guidance Value of 4.5 µg/100ml "	(1) It is recommended that the blood lead level in women of childbearing age does not exceed the reference values of the general population not occupationally exposed to lead in the respective EU Member State. When national reference levels are not available, it is recommended that blood lead levels in women of childbearing age do not exceed the Biological Guidance Value of 4.5 µg/100ml. ***Due to a continuous decline in environmental lead exposure levels, this value shall be revised every five years.*** "	(1) ~~It is recommended that the blood lead level in women of childbearing age does not exceed the reference values of the general population not occupationally exposed to lead in the respective EU Member State. When national reference levels are not available, it is recommended that blood lead levels in women of childbearing age do not exceed the Biological Guidance Value of 4.5 µg/100ml~~ "	