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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	27 November 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 738 final
Subject:	ANNEXES to the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codification)

Delegations will find attached document COM(2023) 738 final – Annexes 1 to 6.

Encl.: COM(2023) 738 final – Annexes 1 to 6

EUROPEAN
COMMISSION

Brussels, 27.11.2023
COM(2023) 738 final

ANNEXES 1 to 6

ANNEXES

to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codification)

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23
→1 2014/27/EU Art. 5.6

ANNEX I

List of substances, →1 mixtures ← and processes
(Article 2, point (a)(ii))

1. Manufacture of auramine.
2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch.
3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
4. Strong acid process in the manufacture of isopropyl alcohol.
5. Work involving exposure to hardwood dusts[1].

↓ 2017/2398 Art. 1.4

6. Work involving exposure to respirable crystalline silica dust generated by a work process.

↓ 2019/130 Art. 1.2

7. Work involving dermal exposure to mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine.
8. Work involving exposure to diesel engine exhaust emissions.

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[1] A list of some hardwoods is to be found in Volume 62 of the Monographs on the Evaluation of Carcinogenic Risks to Humans 'Wood Dust and Formaldehyde', published by the International Agency for Research on Cancer, Lyon, 1995.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23

ANNEX II

Practical recommendations for the health surveillance of workers (Article 15(7))

↓ 2022/431 Art. 1.16 (adapted)

1. The doctor and/or authority responsible for the health surveillance of workers exposed to carcinogens, mutagens or reprotoxic substances ⌦ shall ⌫ be familiar with the exposure conditions or circumstances of each worker.

↓ Corrigendum, OJ L 229, 29.6.2004, p. 23 (adapted)

2. Health surveillance of workers ⌦ shall ⌫ be carried out in accordance with the principles and practices of occupational medicine; it ⌦ shall ⌫ include at least the following measures:

   – keeping records of a worker's medical and occupational history,

   – a personal interview,

   – where appropriate, biological surveillance, as well as detection of early and reversible effects.

   Further tests may be decided upon for each worker when ⌦ the worker ⌫ is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.

↓ 2019/130 Art. 1.3 and Annex (adapted)
→1 2019/983 Art. 1.2 and Annex
→2 2022/431 Art. 1.17 and Annex .1(a)
→3 2022/431 Art. 1.17 and Annex .1(b)
(adapted)

ANNEX III

LIMIT VALUES AND OTHER DIRECTLY RELATED PROVISIONS (ARTICLE 17)

A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation	Transitional measures
			8 hours ([3])			Short-term ([4])				
			mg/m^3 ([5])	ppm ([6])	f/ml ([7])	mg/m^3 ([5])	ppm ([6])	f/ml ([7])		
Hardwood dusts	—	—	2 ([8])	—	—	—	—	—	—	
Chromium (VI) compounds which are carcinogens within the meaning of Article 2, point (a)(i) (as chromium)	—	—	0,005	—	—	—	—	—	—	Limit value 0,010 mg/m^3 until 17 January 2025 Limit value: 0,025 mg/m^3 for welding or plasma cutting processes or similar work processes that generate fume until 17 January 2025
Refractory ceramic fibres which are carcinogens within the meaning of Article 2, point (a)(i)	—	—	—	—	0,3	—	—	—	—	

Respirable crystalline silica dust	—	—	0,1 ([9])	—	—	—	—	—	—	
→2 Benzene ←	→2 200-753-7 ←	→2 71-43-2 ←	→2 0,66 ←	→2 0,2 ←	→2 – ←	→2 – ←	→2 – ←	→2 – ←	→2 Skin ([15]) ←	→2 Limit value 1 ppm (3,25 mg/m^3) until 5 April 2024. Limit value 0,5 ppm (1,65 mg/m^3) from 5 April 2024 until 5 April 2026. ←
Vinyl chloride monomer	200-831-0	75-01-4	2,6	1	—	—	—	—	—	
Ethylene oxide	200-849-9	75-21-8	1,8	1	—	—	—	—	skin ([10])	
1,2-Epoxypropane	200-879-2	75-56-9	2,4	1	—	—	—	—	—	
Trichloroethylene	201-167-4	79-01-6	54,7	10	—	164,1	30	—	skin ([10])	
Acrylamide	201-173-7	79-06-1	0,1	—	—	—	—	—	skin ([10])	
2-Nitropropane	201-209-1	79-46-9	18	5	—	—	—	—	—	
o-Toluidine	202-429-0	95-53-4	0,5	0,1	—	—	—	—	skin ([10])	
4,4′-Methylenedianiline	202-974-4	101-77-9	0,08	—	—	—	—	—	skin ([10])	
Epichlorohydrine	203-439-8	106-89-8	1,9	—	—	—	—	—	skin ([10])	
Ethylene dibromide	203-444-5	106-93-4	0,8	0,1	—	—	—	—	skin ([10])	
1,3-Butadiene	203-450-8	106-99-0	2,2	1	—	—	—	—	—	

Ethylene dichloride	203-458-1	107-06-2	8,2	2	—	—	—	—	skin ([10])	
Hydrazine	206-114-9	302-01-2	0,013	0,01	—	—	—	—	skin ([10])	
Bromoethylene	209-800-6	593-60-2	4,4	1	—	—	—	—	—	
Diesel engine exhaust emissions			0,05 ([*])							For underground mining and tunnel construction the limit value shall apply from 21 February 2026.
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of this Directive									skin ([10])	
Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine									skin ([10])	
➔1 Cadmium and its inorganic compounds ←	➔1 — ←	➔1 — ←	➔1 0,001 ([11]) ←	➔1 — ←	➔1 — ←	➔1 — ←	➔1 — ←	➔1 — ←		➔1 Limit value 0,004 mg/m ([12]) until 11 July 2027 ←

→1 Beryllium and inorganic beryllium compounds ←	→1 — ←	→1 — ←	→1 0,0002 (11) ←	→1 — ←	→1 — ←	→1 — ←	→1 — ←	→1 — ←	→1 dermal and respiratory sensitisation (13) ←	→1 Limit value 0,0006 mg/m3 until 11 July 2026 ←
→1 Arsenic acid and its salts, as well as inorganic arsenic compounds ←	→1 — ←	→1 — ←	→1 0,01 (11) ←	→1 — ←	→1 — ←	→1 — ←	→1 — ←	→1 — ←	→1 — ←	
→1 Formaldehyde ←	→1 200-001-8 ←	→1 50-00-0 ←	→1 0,37 ←	→1 0,3 ←	→1 — ←	→1 0,74 ←	→1 0,6 ←	→1 — ←	→1 dermal sensitisation (14) ←	→1 Limit value of 0,62 mg/m3 or 0,5 ppm (3) for the health care, funeral and embalming sectors until 11 July 2024 ←
→1 4,4′-Methylene-bis (2-chloroaniline) ←	→1 202-918-9 ←	→1 101-14-4 ←	→1 0,01 ←	→1 — ←	→1 — ←	→1 — ←	→1 — ←	→1 — ←	→1 skin (10) ←	
→3 Acrylonitrile ←	→3 203-466-5 ←	→3 107-13-1 ←	→3 1 ←	→3 0,45 ←	→3 – ←	→3 4 ←	→3 1,8 ←	→3 – ←	→3 Skin (10) Dermal sensitisation (14) ←	→3 The limit values shall apply from 5 April 2026. ←
→3 Nickel compounds ←	→3 – ←	→3 – ←	→3 0,01 (15) 0,05 (16) ←	→3 – ←	→3 – ←	→3 – ←	→3 – ←	→3 – ←	→3 Dermal and respiratory sensitisation (13) ←	→3 The limit value (15) shall apply from 18 January 2025 The limit value (16) shall apply from 18 January 2025. Until then a limit value of 0,1 mg/m (16) shall apply. ←
→3 Inorganic lead and its compounds ←			→3 0,15 ←							

→3 N,N-Dimethylacetamide ←	→3 204-826-4 ←	→3 127-19-5 ←	→3 36 ←	→3 10 ←		→3 72 ←	→3 20 ←		→3 Skin ([10]) ←	
→3 Nitrobenzene ←	→3 202-716-0 ←	→3 98-95-3 ←	→3 1 ←	→3 0,2 ←					→3 Skin ([10]) ←	
→3 N,N Dimethylformamide ←	→3 200-679-5 ←	→3 68-12-2 ←	→3 15 ←	→3 5 ←		→3 30 ←	→3 10 ←		→3 Skin ([10]) ←	
→3 2-Methoxyethanol ←	→3 203-713-7 ←	→3 109-86-4 ←		→3 1 ←					→3 Skin ([10]) ←	
→3 2-Methyoxyethyl acetate ←	→3 203-772-9 ←	→3 110-49-6 ←		→3 1 ←					→3 Skin ([10]) ←	
→3 2-Ethoxy ethanol ←	→3 203-804-1 ←	→3 110-80-5 ←	→3 8 ←	→3 2 ←					→3 Skin ([10]) ←	
→3 2-Ethoxyethyl acetate ←	→3 203-839-2 ←	→3 111-15-9 ←	→3 11 ←	→3 2 ←					→3 Skin ([10]) ←	
→3 1-Methyl-2-pyrrolidone ←	→3 212-828-1 ←	→3 872-50-4 ←	→3 40 ←	→3 10 ←		→3 80 ←	→3 20 ←		→3 Skin ([10]) ←	
→3 Mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury) ←			→3 0,02 ←							

→3 Bisphenol A; 4,4′-Isopropylidenediphenol ←	→3 201-245-8 ←	→3 80-05-7 ←	→3 2 ([11]) ←							
→3 Carbon monoxide ←	→3 211-128-3 ←	→3 630-08-0 ←	→3 23 ←	→3 20 ←		→3 117 ←	→3 100 ←			

([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, of Regulation (EC) No 1272/2008.
([2]) CAS No: Chemical Abstract Service Registry Number.
([3]) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).
([4]) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
([5]) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
([6]) ppm = parts per million by volume in air (ml/m^3).
([7]) f/ml = fibres per millilitre.
([8]) Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.
([9]) Respirable fraction.
([10]) Substantial contribution to the total body burden via dermal exposure possible.
→1 ([11]) Inhalable fraction. ←
→1 ([12]) Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a biomonitoring system with a biological limit value not exceeding 0,002 mg Cd/g creatinine in urine. ←
→1 ([13]) The substance can cause sensitisation of the skin and of the respiratory tract. ←
→1 ([14]) The substance can cause sensitisation of the skin. ←
([15]) Respirable fraction, measured as nickel.
([16]) Inhalable fraction, measured as nickel.
(*) Measured as elemental carbon.

B. OTHER DIRECTLY RELATED PROVISIONS

p.m.

↓ 2022/431 Art. 1.17 and Annex point 2 (adapted)

ANNEX IV

BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES

(Article 17(4))

1. Lead and its ionic compounds

1.1. Biological monitoring ⌦ shall ⌫ include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:

70 µg Pb/100 ml blood

1.2. Medical surveillance ⌦ shall be ⌫ carried out if exposure to a concentration of lead in air is greater than 0,075 mg/m^3, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers.

↑

ANNEX V

Part A

Repealed Directive
with [list of the successive amendments thereto/the amendment thereto]
(referred to in Article 25)

Directive 2004/37/EC of the European Parliament and of the Council (OJ L 158, 30.4.2004, p. 50)	
Directive 2014/27/EU of the European Parliament and of the Council (OJ L 65, 5.3.2014, p. 1)	Only Article 5
Directive (EU) 2017/2398 of the European Parliament and of the Council (OJ L 345, 27.12.2017, p. 87)	
Directive (EU) 2019/130 of the European Parliament and of the Council (OJ L 30, 31.1.2019, p. 112)	
Directive (EU) 2019/983 of the European Parliament and of the Council (OJ L 164, 20.6.2019, p. 23)	
Regulation (EU) 2019/1243 of the European Parliament and of the Council (OJ L 198, 25.7.2019, p. 241)	Only point III(12) of the Annex
Directive (EU) 2022/431 of the European Parliament and of the Council (OJ L 88, 16.3.2022, p. 1)	

Part B

Time-limits for transposition into national law and date of application (referred to in Article 25)

Directive	Time-limit for transposition	[Date of application]
Directive 2004/37/EC	31/12/1992; 27/06/2000; 29/04/2003;	20/05/2004
Directive 2014/27/EU	01/06/2015	25/03/2014
Directive (EU) 2017/2398	17/01/2020	16/01/2018
Directive (EU) 2019/130	20/02/2021	20/02/2019
Directive (EU) 2019/983	11/07/2021	10/07/2019
Directive (EU) 2022/431	05/04/2024	05/04/2022

ANNEX VI

CORRELATION TABLE

Directive 2004/37/EC	This Directive
Article 1	Article 1
Article 2, points (a) and (b)	Article 2, points (a) and (b)
Article 2, point (ba)	Article 2, point (c)
Article 2, point (bb)	Article 2, point (d)
Article 2, point (bc)	Article 2, point (e)
Article 2, point (c)	Article 2, point (f)
Article 2, point (d)	Article 2, point (g)
Article 2, point (e)	Article 2, point (h)
Article 3	Article 3
Article 4	Article 4
Article 5(1), (2) and (3)	Article 5(1), (2) and (3)
Article 5(3a)	Article 5(4)
Article 5(3b)	Article 5(5)
Article 5(4)	Article 5(6)
Article 5(5)	Article 5(7)
Article 6	Article 6
Article 7	Article 7
Article 8	Article 8
Article 9	Article 9
Article 10	Article 10
Article 11	Article 11
Article 12	Article 12
Article 13	Article 13
Article 13a	Article 14

Article 14	Article 15
Article 15(1)	Article 16(1)
Article 15(1a)	Article 16(2)
Article 15(2)	Article 16(3)
Article 16	Article 17
Article 16a	Article 18
Article 17	Article 19
Article 17a	Article 20
Article 17b	Article 21
Article 18	Article 22
Article 18a	Article 23
Article 19	Article 24
Article 20	Article 25
Article 21	Article 26
Article 22	Article 27
Annex I	Annex I
Annex II	Annex II
Annex III	Annex III
Annex IIIa	Annex IV
Annex IV	–
Annex V	–
–	Annex V
–	Annex VI