

Revision of the Carcinogens & Mutagens Directive – state of play

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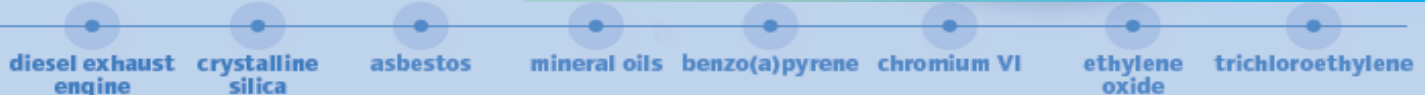
Stop cancer at work

53% of all work-related deaths are caused by occupational cancer.



THESE DEATHS ARE PREVENTABLE

Some of the main carcinogens causing work cancers



50 carcinogens account for more than **80%** of all exposure at work.

5 The current number of binding occupational exposure limit values (OELs) adopted at EU level.



OELs are minimum levels of protection against hazardous substances in the workplace.

There are large differences in the level of protection of workers across the EU. Every country has its own number of OELs, and often different levels for the same substance.

Binding OELs are one of the essential tools for minimizing the exposure levels.

The ETUC calls on the EU to urgently update the Carcinogens and mutagens directive and adopt binding OELs for at least 50 priority carcinogens

Content

- ❑ First batch of 11 (+2) carcinogens: state of play ?
 - ❑ Adopted in Directive (EU) 2017/2398

- ❑ Second batch of 5 (+2) carcinogens : state of play ?
 - ❑ Adopted in Directive (EU) 2019/130

- ❑ Third batch: state of play ?

- ❑ Fourth batch: state of play ?

- ❑ Substances toxic for reproduction ?

Revision of the Carcinogens & Mutagens Directive

- ❑ Since the adoption of the CMD in 1990 only 3 carcinogens with Binding Occupational Exposure Limits (BOELs)

Directive (EU) 2017/2398

Directive (EU) 2019/130

Directive (EU) 2019/983

1st batch
(11+2 BOELs)

2nd batch
(6 BOELs)

3rd batch
(5 BOELs)

4th batch
?

2017

2018

2019

?

- ❑ Commissioner Thyssen commitment: 50 carcinogens in total with BOELs in CMD Annex III by 2020

First batch adopted in December 2017 (Dir 2017/2398)

Chemical agents	Proposed OELs	Relevant sectors	Types of cancer caused/other illnesses	No. of exposed workers
1,2- Epoxypropane	2.4 mg/m ³	Chemical manufacture; synthetic lubricants, oil field drilling chemicals; polyurethane systems.	Lymphopoietic cancer, haematopoietic cancer, increased leukaemia risk	485-1,500
1,3-Butadiene	2.2 mg/m ³	Manufacture of refined petroleum products, manufacture of rubber products	Lymphohaema-topoietic cancer	27,600
2-Nitropropane	18 mg/m ³	Manufacture of basic chemicals, manufacture of aircraft and spacecraft (downstream use)	Liver tumours	51,400
Acrylamide	0.1 mg/m ³	Manufacture of chemicals and chemical products, education, research and development, other business activities, health and social work, public administration and defence.	Pancreatic cancer	54,100
Bromoethylene	4.4 mg/m ³	Chemicals and allied production; rubber and plastic production; leather and leather production; fabricated metal production for wholesale trade	Liver cancer	n/a
Chromium (VI) compounds	0.005 mg/m ³ (5y transition 0.01 mg/m ³)	Production and use of chromium-containing pigments, paints and metal (conversion) coatings. In terms of downstream use, chromate compounds, including barium chromate, zinc chromate, and calcium chromate, may be used as basic primers and top coats in the aerospace sector.	Lung cancer and sinonasal cancer	916,000
Ethylene Oxide	1,8 mg/m ³	Extraction of crude petroleum and natural gas; service activities incidental to oil and gas extraction; Manufacture of food products, textiles, chemicals, chemical products, medical, precision and optical instruments, watches, clocks; Hospital and Industrial sterilization; R&D; Public Administration and Defence; Education; Health and Social Work	Leukaemia	15,600
Hydrazine	0.013 mg/m ³	Chemical blowing agents; agricultural pesticides; water treatment	Lung and colorectal cancer	2,124,000
o-Toluidine	0.5 mg/m ³	Manufacture of chemicals, chemical products and man-made fibres; Manufacture of rubber products; Research and development; Public administration and defence; education; health and social work.	Bladder cancer	5,500
Respirable Crystalline Silica (RCS)	0.1 mg/m ³ (to be reviewed)	Mining, glass manufacturing, construction and electricity, gas, steam and hot water supply industries.	Lung cancer, silicosis	5,300,000
Refractory Ceramic Fibres (RCF)	0.3 f/ml	Manufacturing (fibre production, finishing, installation, removal, assembly operations, mixing/forming)	Adverse respiratory effects, skin and eye irritation; possibly lung cancers	10,000
Vinyl Chloride Monomer (VCM)	2.6 mg/m ³	Manufacture of chemicals and chemical products (VCM and PVC production)	Angiosarcoma, hepatocellular carcinomas	15,000
Hardwood dusts	2 mg/m ³ (5y transition 3 mg/m ³)	Wood working industry, furniture manufacture sectors and construction.	Sinonasal and nasopharyngeal cancers	3, 333,000

2nd batch adopted in October 2018 (Dir 2019/130)

Chemical agents	Binding OELs	Relevant sectors	Types of cancer caused/other illnesses	No. of exposed workers
4,4'-methylenedianiline (MDA)	0,08 mg/m ³ (+ skin notation in Annex III)	Production of polyurethane foams	Liver and thyroid cancer in animal studies. Also: suspected of causing genetic defects, causes damages to organs,...	390,000 – 3,900,000
Trichloroethylene (TCE)	54,7 mg/m ³ (+ skin notation in Annex III)	Degreasing and cleaning of metal parts Used in adhesives, Used as a solvent and for synthesis in the chemical industry.	Liver cancer, Kidney cancer. Also: suspected of causing genetic defects, causes serious eye irritation, causes skin irritation, ...	74,000
Epichlorohydrin (1-Chloro-2,3-epoxypropane)	1,9 mg/m ³ (+ skin notation in Annex III)	Chemical industry (production of resins) Paper production	Lung cancer. Also: toxic if inhaled, toxic in contact with skin, toxic if swallowed...	40,000
Ethylene dibromide (EDB) (Dibromoethane)	0.8 mg/m ³ (+ skin notation in Annex III)	Chemical industry Preparation of dyes and pharmaceuticals	Caused tumors in animal studies. Also: toxic if swallowed, toxic in contact with skin, toxic if inhaled	7,600
Ethylene dichloride (EDC) (1,2-Dichloroethane)	8,2 mg/m ³ (+ skin notation in Annex III)	Production of plastic and vinyl products Also used as a solvent and added to leaded gasoline to remove lead.	Caused tumors in animal studies. Also: harmful if swallowed, causes serious eye irritation, causes skin irritation...	< 3,000
Diesel engine exhaust emission	0.05 mg/m ³ (as of 21-02-2023)	Transport, vehicle repair, construction, tunneling, agriculture, etc.	Cause tumors in animal studies, lung cancer	3.600,000
Complex PAH mixtures with benzo[a]pyrene as an indicator	None (skin notation in Annex III only)	Coal liquefaction, coal gasification, coke production and coke ovens, coal-tar distillation. Roofing and paving (involving coal-tar pitch) Wood impregnation and preservation. Aluminium production Carbon-electrode manufacture. Chimney sweeping	Tumors in animal studies Also: may cause an allergic skin reaction, genetic defects, damage fertility & the unborn child.	7,000,000
Used engine oils	None (entry in Annex I + skin notation in Annex III)	Used in automobile and motorcycle engines, diesel rail engines, marine engines, aeroengines, and in portable machinery including chain saws and lawn mowers	Skin cancer	1,000,000

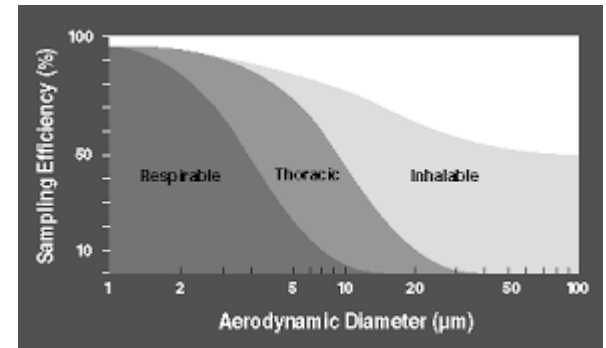
3rd batch adopted in January 2019 (Dir 2019/983)

Chemical agents	Binding OELs	Relevant sectors	Types of cancer caused/other illnesses	No. of exposed workers
Cadmium and its inorganic compounds	0,001 mg/m ³ (8 y transition at 0.004 mg/m ³) + Biomonitoring in urine	Cadmium production and refining, nickel-cadmium battery manufacture, cadmium pigment manufacture and formulation, cadmium alloy production, mechanical plating, zinc and copper smelting, mining of non-ferrous metal ores, etc...	Lung cancer, bladder cancer, kidney cancer and prostatic cancer Proteinuria, osteoporosis and respiratory effects	2,900 – 300,000
Beryllium and inorganic beryllium compounds	0,0002 mg/m ³ (7 y transition at 0,0006 mg/m ³)	Foundries, glass sector, laboratories.	Lung cancer, Chronic beryllium disease, allergy or asthma symptoms, beryllium respiratory and skin sensitisation, cardiovascular, renal effects, etc.	14,000 - 74,000
Arsenic acid and its salts, as well as inorganic arsenic compounds	0,01 mg/m ³ (4 years extra transposition for the copper smelting sector)	Copper and zinc production, glass, electronics and chemical sectors	Lung cancer, skin cancer, liver cancer, lung cancer, bladder cancer, kidney cancer Peripheral neuropathy, cardiovascular effects and immunotoxicity, skin changes, etc	7,900 - 15,300
Formaldehyde	0,37 mg/m ³ (+ notation on dermal sensitisation)	Formaldehyde manufacturing, building and construction works, manufacturing of leather and fur, pulp, paper and paper products, textile and wood and wood products, autopsy rooms	Nasopharyngeal cancer, leukaemia tumor induction Sensory irritation, potential cancer precursor effects	990,000 – 2,200,000
4,4-Methylene-bis(2-chloroaniline) MOCA	0,01 mg/m ³ (+ skin notation in Annex III)	Plastics sector	Lung cancer, bladder cancer	350

3rd batch and final solution adopted for cadmium

- during transitional period
(= 8 years after entry into force):

Option 1 = BOEL of $4 \mu\text{g}/\text{m}^3$ (**inhalable fraction**)



Option 2 = only for MS that implement a biomonitoring system with a Biological limit value (BLV) not exceeding $2 \mu\text{g Cd} / \text{g creatinine}$ in urine:

BOEL of $4 \mu\text{g}/\text{m}^3$ (**respirable fraction**) + BLV of $2 \mu\text{g Cd}/\text{g creatinine}$ in urine

- after transitional period : BOEL of $1 \mu\text{g}/\text{m}^3$ (**inhalable fraction**)
- no later than 3 years after eif, COM shall assess the option of amending CMD to add provisions on a combination of an airborne OEL with a biological limit value for cadmium and its inorganic compounds (new § in Art 18a)

3rd batch : additional amendments adopted

- ❑ **Cytostatic drugs:** No later than the end of Q2 2020 the COM shall [...] assess whether to amend the CMD to include hazardous drugs, including cytostatic drugs, or to propose a more appropriate instrument for the purpose of ensuring occupational safety for workers [...] COM shall present, if appropriate, [...] a legislative proposal (new § in Art 18a)
 - ❑ **CMD Scope clarification** (new recital 2a): [...] The substances meeting the criteria for classification as a category 1A or 1B carcinogen or mutagen set out in Annex I to regulation (EC) No1272/2008 are those with a harmonised classification or classified in accordance with Article 4 or 36 thereof and notified to the ECHA pursuant to Article 40 thereof. [...]
- = substances with harmonised classification + substances with self-classification

Fourth batch: state of play ?

- ❑ Only 3 carcinogens :
 - ✓ Acrylonitrile (33 000 exposed workers)
 - ✓ Nickel compounds (79 000 exposed workers)
 - ✓ Benzene (update of existing BOEL, 1 000 000 exposed workers)

- ❑ Draft ACHS opinions adopted by ACHS on 04 June 2019:

Acrylonitrile

BOEL (8h TWA) = 1 mg/m³ (transition period of 4 years after entry into force)

BOEL (STEL) = 4 mg/m³ (transition period of 4 years after entry into force)

notation: skin

Nickel compounds

BOEL (8h TWA , inhalable fraction) = 0.05 mg/m³ applying from Jan 2025,
until then a transitional OEL of 0.1 mg/m³

BOEL (8h TWA, respirable fraction) = 0,010 mg/m³ applying from Jan 2025

notation: skin and respiratory sensitisation

Benzene

BOEL (8hTWA) = 0,5 ppm (applying after a transition period of 2 y after eif

BOEL (8hTWA) = 0,2 ppm (applying after a transition period of 4 y after eif

By 2028 COM will start to assess the feasibility to reduce further the

BOEL and by 2030 propose CMD amendement where relevant

notation : skin

Next steps ?

- ❑ **CMD1: Transposition of Dir 2017/2398 by 17 January 2020**
- ❑ **CMD2: Transposition of Dir 2019/130 by 20 February 2021**
- ❑ **CMD3: Transposition of Dir 2019/983 by 11 July 2021**
- ❑ **CMD4:**
 - ✓ COM Impact Assessment should be available by end 2019
 - ✓ New COM from Nov 2019 (priorities ?)
 - ✓ Possible COM proposal and adoption of CMD4 in 2020
- ❑ **CMD5:**
 - ✓ New OELs for Cobalt compounds, asbestos, Man made mineral fibres ?
 - ✓ Scope extension to Reprotox substances ?

Thank you for your attention !

More info on:

<https://www.etui.org/Topics/Health-Safety-working-conditions/Occupational-cancers>

<https://www.etuc.org/en/issue/health-safety>

<https://roadmaponcarninogens.eu/>