Recent developments on the CMD revision

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Firefighters' network meeting

Brussels, 13 December 2018

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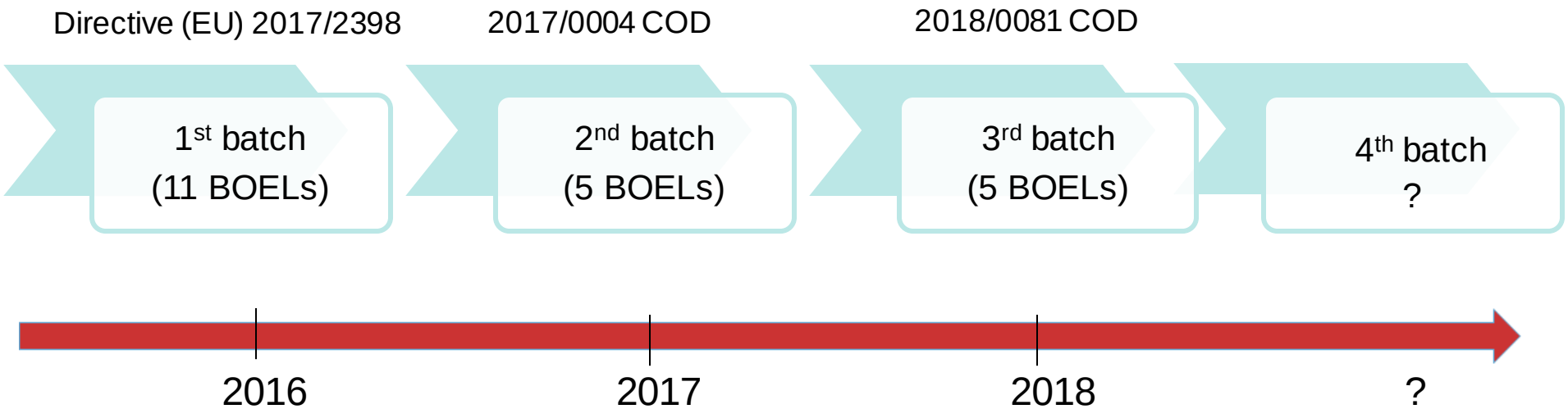
Revision of the Carcinogens & Mutagens Directive

- Since the adoption of the CMD in 1990 only 14 (3 +11) carcinogens with Binding Occupational Exposure Limits (BOELs)



- 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

COM proposal of 10 Jan 2017 (2017/0004 COD) = batch 2

Chemical agents	Proposed 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 tumours 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 tumours in animal studies. Also: harmful if swallowed, causes serious eye irritation, causes skin irritation…	< 3,000
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	Tumours 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

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Batch 2: agreement between the Parliament and the Council on 10 October 2018

- All COM proposals adopted
- + major improvement on Diesel Engines Exhaust Emission
  - In annex 1 (scope of appplication of the CMD). It means that the obligations of the CMD will apply: substitution, minimization, registration of exposures, etc…
  - In annex 3: BOEL of 0,05 mg/m3 (Elemental Carbon)
- Minimal requirements
- 3,6 million workers affected by DEEE

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COM proposal 2018/0081(COD) of 5 April 2018 = batch 3

Chemical agents	Proposed OELs	Relevant sectors	Types of cancer caused/other illnesses	No. of exposed workers
Cadmium and its inorganic compounds	0,001 mg/m³ (7 y transition at 0.004 mg/m³)	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 Proteinurea, osteoporosis and respiratory effects	2,900 – 300,000
Beryllium and inorganic beryllium compounds	0,0002 mg/m³ (5 y transition at 0,0006 mg/m³)	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/m³ (2 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/m³ (+ 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/m³ (+ skin notation in Annex III)	Plastics sector	Lung cancer, bladder cancer	350

Batch 3: Amendments voted by the Parliament on 20 November 2018

- Amendments with a positive impact :
  - hazardous drugs : COM to envisage a legislative initiative by end of 2019 to better protect workers in health sector (12,7 million workers in the EU)
  - clarifying the Directive's scope on which are the Carc & Mut cat 1A/1B covered. The amendment also calls for improved cooperation with the International Agency for Research on Cancer (IARC)

- Amendments with a potential negative impact :
  - Biological Limit Value on cadmium: MS to choose between two legislative options: strict OEL or less strict OEL + BLV

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Fourth batch: state of play ?

- COM proposal by end 2019?
  - ✓ All necessary steps incl. Impact Assessment should be available in 2019
  - ✓ Juncker Commission will end in 2019
  - ✓ Priorities of next Commission might change

- Expected carcinogens (based on scientific recommendation from RAC):
  - ✓ Nickel compounds
  - ✓ Acrylonitrile
  - ✓ Benzene (update of existing BOEL)
  - ~~✓ Diesel engine exhaust emissions~~ (already agreed in batch 2)

- ACHS opinions not yet adopted

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Next steps for trade unions ?

Batch 1 & 2 : make sure transposition at national level in all Member States is ambitious (minimum requirements !)

Batch 3:

- Define a common TU position on the amendments
- Intervene with MEPs and with national authorities
- In the Council : different positions
- Launch a longer term debate on biological limit values

Batch 4: on going work in the Advisory Cttee on Health & Safety

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Joint declaration on reprotoxix substances – 18 October 2018

https://www.etuc.org/en/pressrelease/chemical-industry-and-workers-call-european-commission-update-eu-rules-reprotoxic

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EU OSH legislation & reprotoxic (R) substances?

- **Chemical Agents Directive- CAD (98/24/EC):** applies to all hazardous chemicals present at the workplace (including R substances)

- **Carcinogens & Mutagens Directive - CMD** (2004/37/EEC): applies solely to substances meeting the criteria for classification as Carcinogen (C) or Mutagens (M) category 1A (known) or 1 B (presumed)

- Under Article 18a of Dir(EU) 2017/2398 (CMD 1 revision): "*No later than Q1-2019, the* ***COM shall*** *[…]* ***assess the option*** *of* ***amending the scope of this Directive to include reprotoxic substances****."*

- COM has commissioned an impact study to evaluate different options

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The 5 options considered in COM impact study

Option 1: No change to EU OSH legislation (CAD and CMD) = **baseline**

Option 2: R1A and 1B chemicals included in the scope of CMD with **full application of the requirements in the CMD**

Option 3: R1A and 1B included in the scope of the CMD **but with derogations** from the substitution, closed systems, minimisation and record keeping requirements, unless an EU scientific committee confirms that a substance has no threshold.

Option 4: **Merging** the CMD and CAD into a single directive, applying CMD-equivalent requirements to R 1A/1B substances

Option 5: **Merging** the CMD and CAD into a single directive, applying CMD-equivalent requirements to R 1A/1B **substances and updating/modernising OSH-related terminology**

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The joint declaration ETUC / industriAll / ECEG / Cefic

- signed on 16 October 2018

Common agreement from both sides of industry for:

- **inclusion** of Reprotoxics in the CMD scope = CM**R**D instead of CMD

- **same rules** for **C**arcinogens, **M**utagens & **R**eprotoxics cat 1A/B

(Elimination/substitution > Closed system > Exposure minimisation)

- **distinction** between threshold & non-threshold substances

- **derogation** to the exposure minimisation **only for threshold substances** when :
  - a Binding OEL is available at EU level
  - the BOEL is complied with (= exposure measurements)

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Concrete result of the joint declaration = new option 3 bis

Option 1: No change to EU OSH legislation (CAD and CMD) = **baseline**

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Option 3bis: ETUC/indutriAll/ECEG/Cefic joint declaration

Option 4: **Merging** the CMD and CAD into a single directive, applying CMD-equivalent requirements to R 1A/1B substances

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Next steps to have the joint demands integrated in the CMD?

- Opinion of the tripartite Advisory Cttee on Health & Safety
- COM consultation of the social partners on the CMD revision (2 phases)
- COM impact study on the proposed changes (~ the current study ?)
- COM legislative proposal
- Co-decision procedure (European Parliament + Council) = CMD5?

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Further information on occupational cancers:

- **ETUI book: Work and Cancer, understanding occupational cancers and taking action to eliminate them:**

https://www.etui.org/Publications2/Books/Cancer-and-work-understanding-occupational-cancers-and-taking-action-to-eliminate-them

- **HESAMAG n° 18**: thematic issue on cancer at the workplace :

https://www.etui.org/Topics/Health-Safety-working-conditions/HesaMag

- **EU-OSHA Campaign** Manage Dangerous Substances 2018-2019: https://healthy-workplaces.eu/en/campaign-partners/european-trade-union-confederation

- **EU Roadmap on carcinogens**: https://roadmaponcarcinogens.eu/

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