

# Q&A ON DIRECTIVE 2004/37/EC

## Q&A ON DIRECTIVE 2004/37 EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE PROTECTION OF WORKERS FROM THE RISKS RELATED TO EXPOSURE TO CARCINOGENS OR MUTAGENS AT WORK

Document prepared by Concawe Health Management Group



### Part 1: General

<sup>1</sup> [http://europa.eu/rapid/press-release\\_IP-16-1656\\_en.htm](http://europa.eu/rapid/press-release_IP-16-1656_en.htm)

#### What is the aim of the Carcinogens and Mutagens Directive (CMD)?

Cancer is the leading cause of work-related deaths in the EU accounting for 53% of all work-related deaths<sup>1</sup>. So far, four amendments to the Carcinogens and Mutagens Directive (2004/37/EC) have been scheduled with the aim to limit exposure to an increasing number of such substances. In this context, the scope of the Directive has been expanded and occupational exposure limits (OELs) have been revised for several carcinogens (see Annex I for OEL setting process). As a result of the 3<sup>rd</sup> amendment, 27 carcinogens are listed in Annex III of CMD. With the 4<sup>th</sup> amendment, the list will contain a minimum of 29 carcinogens.

The CMD sets general provisions to prevent or reduce exposure for all carcinogens and mutagens falling under its scope, i.e. for substances classified as carcinogens and mutagens Category 1 according to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP). It also applies to the so-called 'process-generated substances' (PGS). These are carcinogens generated during combustion, e.g. diesel engine exhaust, or as by-products during production processes, e.g. hardwood dust. PGS are not subject to the CLP classification system (neither to REACH Regulation) because they are never 'placed on the market' in the EU.

Note: in bold the carcinogens more relevant for the Refining Industry.

## What is the timeline of the CMD revisions?

- 1<sup>st</sup> amendment: published in December 2017 ([Directive](#) (EU) 2017/2398).
- 2<sup>nd</sup> amendment: published in January 2019 ([Directive](#) (EU) 2019/130).
- 3<sup>rd</sup> amendment: published in June 2019 ([Directive](#) (EU) 2019/983).
- 4<sup>th</sup> amendment: will include Nickel compounds and revision to the Benzene OEL.

## What is a “binding” OEL?

OELs established for carcinogens are “binding”: they must be adopted as minimum standards by Member States. Therefore, Member States must establish a corresponding national binding occupational exposure limit value, lower or equal to the EU OEL.

## Which carcinogens were included in the 1<sup>st</sup> amendment of the CMD?

14 Carcinogens were included in [Directive](#) (EU) 2017/2398 of 12 December 2017:

- 1,2-Epoxypropane;
- **1,3-Butadiene;**
- 2-Nitropropane;
- Acrylamide;
- Bromoethylene;
- Chromium (VI) compounds;
- Ethylene Oxide;
- Hardwood dusts - OEL updated;
- Hydrazine;
- o-Toluidine;
- Respirable Crystalline Silica (RCS);
- Refractory Ceramic Fibres (RCF);
- Vinyl Chloride Monomer (VCM) - OEL updated;
- **Benzene – OEL unchanged in the amendment.**

## Which carcinogens were included in the 2<sup>nd</sup> amendment of the CMD?

8 additional carcinogens were included in [Directive](#) (EU) 2019/130 of 16 January 2019:

- 4,4-methylenedianiline;
- Epichlorohydrine;
- Ethylene dibromide;
- Ethylene dichloride;
- Trichloroethylene;
- **Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of the Directive [no OEL proposed but a skin notation<sup>2</sup>];**
- **Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts [no OEL proposed but a skin notation];**
- **Diesel engine exhaust emissions [OEL= 50 µg/m<sup>3</sup> elemental carbon (8-h TWA) applicable from 2023].**

<sup>2</sup> Skin notation indicates potential substantial contribution to the total body burden via dermal exposure

Note: in bold the carcinogens more relevant for the Refining Industry.

## Which carcinogens were included in the 3<sup>rd</sup> amendment of the CMD?

5 additional carcinogens were included in [Directive](#) (EU) 2019/983:

- Cadmium and its inorganic compounds;
- Beryllium and its inorganic compounds;
- Arsenic acid and its salts, as well as inorganic arsenic compounds;
- Formaldehyde;
- 4,4'-methylene-bis(2-chloroaniline) (MOCA).

## What will be the changes in the 4<sup>th</sup> amendment of the CMD?

- **Nickel compounds** will be included;
- Acrylonitrile will be included;
- **Benzene OEL** will be revised.

## Are Biological Limit Values (BLVs) included in the CMD?

No, currently BLVs are not proposed under the CMD; it only includes general provisions recommending to carry out the health surveillance of workers in accordance with the principles and practices of occupational medicine which includes, where appropriate, biological surveillance as detection of early and reversible effects.

## Does the Directive distinguish between threshold and non-threshold carcinogens?

Although the scientific studies are evidencing that many of the carcinogens only have an adverse effect above a threshold, the published Amendments do not differentiate the measures to be applied by the employer to reduce risk when the potential exposure is to a threshold carcinogen, with negligible or no residual risk, or to a non-threshold carcinogen.

## Future work on OELs

The European Commission and the European Chemicals Agency (ECHA) have signed an [agreement](#) for the Agency to provide recommendations on a regular basis for OELs that protect workers exposed to hazardous chemicals. The agreement requires ECHA to assess four to five OELs per year from 2020 onwards.

### A. DIESEL ENGINE EXHAUST EMISSIONS (DEEE)

#### Why were Diesel engine exhaust emissions (DEEE) included in the 2<sup>nd</sup> amendment of the CMD?

DEEE was added to the list of carcinogens included in the 2<sup>nd</sup> amendment of the CMD by the co-legislators. DEEE is a PGS and therefore not subject to the CLP classification system. DEEE has been classified by IARC as carcinogenic to humans (IARC category 1). It is considered to impact a number of exposed workers ranging from 8 000 000 to 19 000 000 in the EU. The types of cancer caused were lung cancer and bladder cancer. Examples of sectors concerned: Mining (underground and above ground) - Professional drivers (road and railway) - Road construction - Tunnel construction - Dock and warehouse workers - Garage and rail car maintenance workers.

#### What is the OEL for DEEE?

The OEL for diesel engine exhaust is 50 µg/m<sup>3</sup> as elemental carbon (EC). There is a transitional period since the limit value shall apply from 21 February 2023. For underground mining and tunnel construction, the limit value shall apply from 21 February 2026. EC is considered a marker of exposure to DEEE.

## Part 2: Carcinogens relevant for the Refining Industry

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<sup>3</sup> More technical details can be found at: <https://www.cdc.gov/niosh/docs/2003-154/pdfs/chapter-q.pdf>

## How do I measure occupational exposure to DEEE?

NIOSH has published a method ([Method 5040](#))<sup>3</sup> based on a thermal-optical analysis technique for particulate carbon as EC.

## What are the typical occupational exposure levels to DEEE?

According to [IARC Monograph](#) (2013; Vol 105, pg. 82-90), typical occupational exposure levels to DEEE are:

- Transport: < 50 µg/m<sup>3</sup> EC;
- Mining: 100 – 600 µg/m<sup>3</sup> EC;
- Construction, main exposures in tunneling works.

## What is the impact of including DEEE in CMD for Concawe member companies?

Considering the DEEE typical occupational exposure levels and corresponding OEL of 50 µg/m<sup>3</sup> EC (8-h TWA), indoor use of diesel engine without appropriate exhaust removal system could be critical. Therefore, Risk Management Measures (RMMs) and Operational Conditions in place should be reviewed.

### **B. MINERAL OILS THAT HAVE BEEN USED BEFORE IN INTERNAL COMBUSTION ENGINES TO LUBRICATE AND COOL THE MOVING PARTS (DESCRIBED BELOW AS ‘USED ENGINE OILS’)**

#### Is there an OEL for “used engine oils”?

Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts are PGS included in the 2<sup>nd</sup> amendment of the CMD. There is no OEL but a skin notation.

#### What is the impact of including “used engine oils” in CMD for Concawe member companies?

RMMs in place for tasks involving dermal contact with “used engine oils” should be reviewed to assess the efficiency of RMMs to minimize the potential for dermal exposure and ensure safe use.

### **C. POLYCYCLIC AROMATIC HYDROCARBONS (PAH) MIXTURES, PARTICULARLY THOSE CONTAINING BENZO[A]PYRENE, WHICH ARE CARCINOGENS WITHIN THE MEANING OF THE DIRECTIVE**

#### Is there an OEL for “PAH mixtures”?

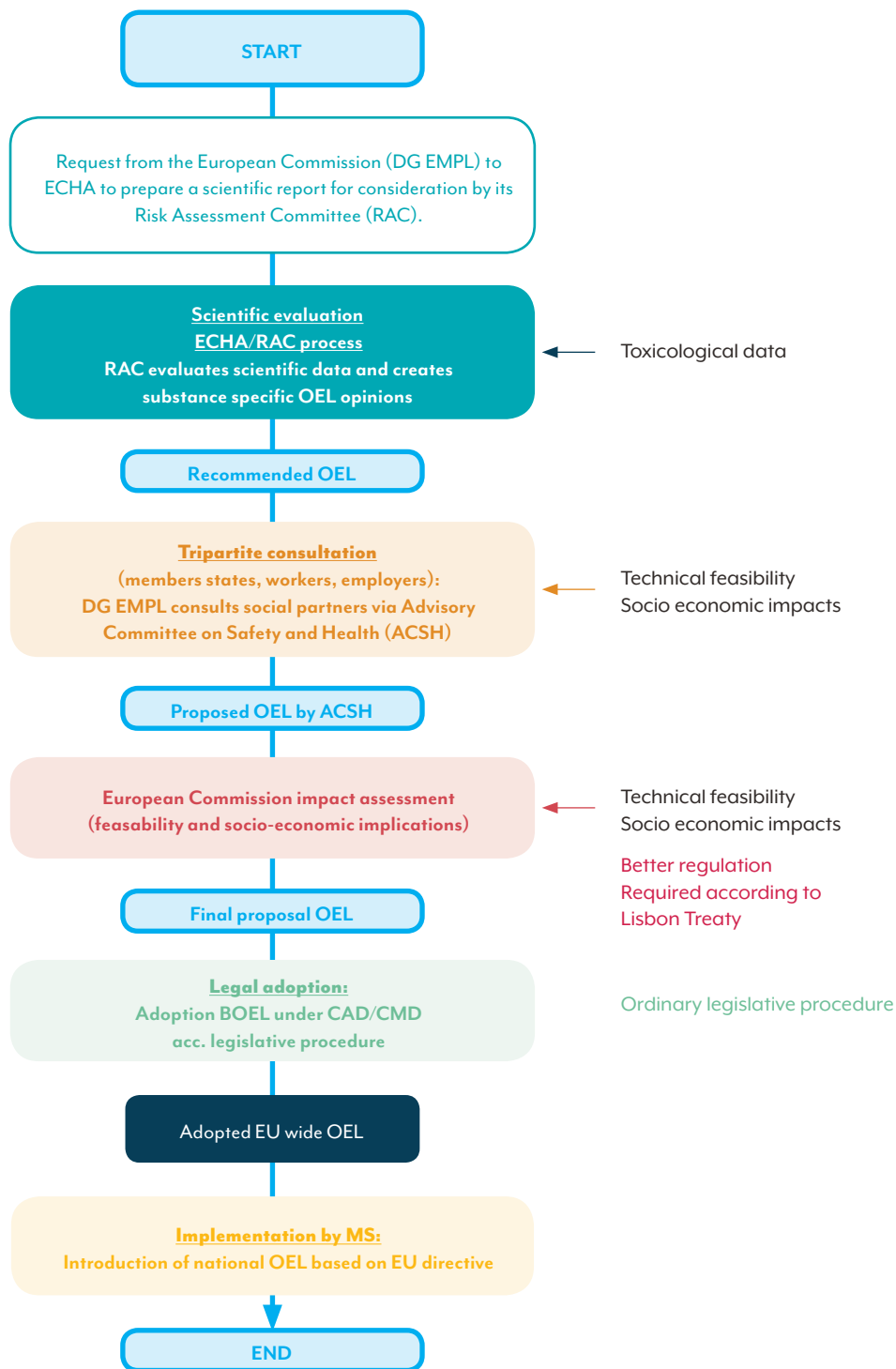
PAH mixtures as PGS are included in the 2<sup>nd</sup> amendment of the CMD. There is no OEL but a skin notation. According to the CMD, further studies should be carried out that might lead to a limit value for PAH mixtures.

#### What is the impact of including “PAH mixtures” in CMD for Concawe member companies?

PAH mixtures as PGS are likely to occur whenever organic material is subject to combustion, e.g. maintenance of furnaces. Any routine or maintenance task involving contact with such material should be reviewed to assess the efficiency of RMMs to minimize the potential for dermal exposure and ensure safe use.

# Annex I

## The EU process to set an OEL



Y0 Y1 Y2 Y3 Y4 Y5 Y6

3 - 5 years to have an EU wide OEL adopted. Depending on the number of substances to be included.

