

The aim of this Brief is to shed light on the need to revamp the current system to set Occupational Exposure Limits (OELs) in [Directive 2004/37/EC](#) on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD).

### **Occupational exposure limits (OELs): a definition**

OELs are a quantitative benchmark for occupational exposure to hazardous chemicals in the workplace, including carcinogens. They are set to prevent occupational diseases like occupational cancers or other adverse effects in exposed workers. Employers use OELs as a tool to assess the risks for exposed workers and select appropriate preventive measures. The EU OELs set under the CMD are binding and employers must, according to the exposure minimisation principle, reduce the exposure of workers as far as technically possible below these limits. As such, binding OELs provide clarity and certainty regarding the maximum level of exposure allowed. For example, the binding OELs for **trichloroethylene**, a carcinogenic solvent, is 54.7 mg/m<sup>3</sup>. When the main route of exposure is not inhalation but, rather dermal absorption, Biological Limit Values can be used in combination to airborne OELs to assess the risks for exposed workers.

### **Threshold and non-threshold carcinogens**

Carcinogens can be divided into two groups depending on their mode of action for carcinogenicity. For “threshold carcinogens” it is possible to identify a single exposure level below which no carcinogenic effect is expected. For “non-threshold carcinogens”, every level of exposure, however low, brings a risk of developing cancer. **Formaldehyde** is, for example, a **threshold carcinogen** whereas **chromium VI** or **1.3-butadiene** are **non-threshold carcinogens**.

### **Health-based and risk-based OELs**

The distinction between threshold and non-threshold carcinogens is important with respect to the type of OELs which can be set under the CMD as well as how its exposure minimisation principle could be interpreted in the future.

For **threshold carcinogens**, provided that the exposure level preventing the development of cancer is also protecting workers against potential other adverse effects, it might be possible to define a so-called “**health-based OEL**”. Workers repeatedly exposed throughout their

working life to exposure level at or below the health-based OEL should suffer no adverse effects on their health or that of their descendants at any time.

For **non-threshold carcinogens**, it is also possible to set OELs, but they will necessarily be associated with a certain risk of developing cancer. In this case, the OEL is called a “**risk-based OEL**” and the risk of developing cancer will depend on the exposure level at which the OEL is set (the higher the exposure, the higher the risk). The binding OEL for **ethylene oxide**, a non-threshold carcinogen, has been set in the CMD at 1.8 mg/m<sup>3</sup>. The additional cancer risk at that level of exposure is 4 10<sup>-3</sup>, meaning that, statistically, 4 out of 1000 workers exposed to this substance throughout their working life will develop cancer.

### **Why do we need to revamp the current methodology to set OELs under the CMD?**

The pressing issue of updating and ameliorating the present mechanism to set binding OELs under the CMD is demanded by European legislation in Article 168 of the TFEU that states: “*A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*”. Until now, the methodology used to derive OELs has repeatedly violated such principle by setting binding OELs on some carcinogens with a very high level of risk. For example, for **chromium VI** the binding OEL proposed by the European Commission in the CMD was 0.025 mg/m<sup>3</sup>. At that level of exposure, the additional cancer risks are **one cancer in 10 exposed workers** which is **unacceptably high!** Thanks to an amendment of the European Parliament, this binding OEL was reduced to 0.005 mg/m<sup>3</sup> with a transitional limit value of 0.010 mg/m<sup>3</sup> until 17 January 2025. For welding processes, unfortunately, the binding OEL during this transitional period will remain at 0.025 mg/m<sup>3</sup> (see Annex I)

Every EU Member State has its own number of national OELs, and for the same substance, they often differ from one country to another. There are therefore large differences in the level of protection of workers across the EU. The binding OELs adopted in the CMD are important, as they oblige each EU Member State to set the same level (or a stricter one) at the national level.

The problem is that the CMD does not set out the method that must be used to develop the OELs. Its article 16.1 only states that OELs shall be set “*on the basis of available information, including scientific and technical data*”. In practice, the current methodology used by the European Commission takes into account a mix of health aspects, technical feasibility and socio-economic factors. Ultimately, the binding OELs proposed for carcinogens are based on cost-benefit analysis. This system is unsatisfactory as it contains several drawbacks that need to be addressed:

- The use of **cost-benefit analysis** to decide on OELs is **morally questionable**. The number of future cancers avoided in exposed workers is compared to the OEL compliance costs for companies, which is like comparing apples to pears. Moreover, benefits are systematically underestimated and, depending on which non-carcinogenic effects are considered in the cost-benefit analysis, the derived OEL will differ from one jurisdiction to another. For example, the binding OEL for **Respirable crystalline silica** is more protective in the US legislation compared to the EU legislation (0.05 mg/m<sup>3</sup> in [US-OSHA standard](#) vs 0.1 mg/m<sup>3</sup> in European CMD)
- the current methodology does not make a difference between threshold and non-threshold carcinogens
- the additional cancer risks associated with the OELs listed in CMD Annex III are not displayed and might give workers a false impression of protection when the OEL is met
- for some of the recent decisions on binding OELs the level of protection differ substantially from one carcinogen to another (e.g. **100 cancers in 1000** exposed workers for **chromium VI** in welding processes versus **4 cancers in 1000** exposed workers for **ethylene oxide**)
- there is no incentive to minimise the exposure below a binding OEL as required by Article 5(3) of the CMD legal text. Some Member States have solved this problem by introducing in their national legislation a mandatory “action plan” (see hereunder for the details)

## Which methodology should be used to set OELs under the CMD?

- **Health-based limit values for threshold carcinogens**

If a threshold mode of action exists, it should be possible to define a level of exposure below which no carcinogenic effect is expected. If this exposure level is also sufficiently protective against other potential adverse effects of the substance, the binding OEL should be set at that level.

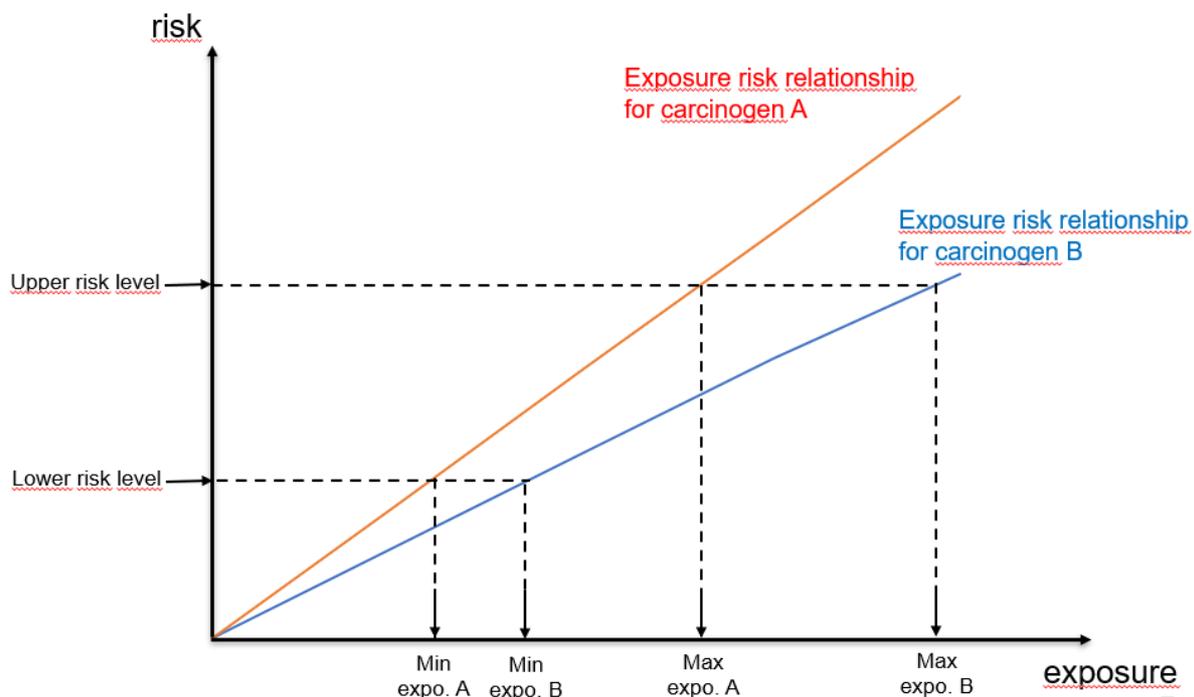
- **Risk-based limit value for non-threshold carcinogens**

For substances without a threshold, the methodology used to set binding OELs should follow a risk-based approach. In this context, the OEL is set at an exposure level corresponding to a risk in the range between an upper risk level and a lower risk level (see figure 1 hereunder).

These two risk levels are **substance-independent** and should be **predefined**. Indeed, while the relationship between levels of exposure to a non-threshold carcinogen and the corresponding risks of developing cancer (so-called “exposure risk-relationship”) can be scientifically determined, the definition of what constitutes an acceptable upper risk level and a lower risk level is a political decision that calls for a societal debate.

In some EU Member States (i.e. Germany, The Netherlands), a risk-based approach is being used for many years to set national OELs for carcinogens. This methodology also describes employers' obligations when the exposure is above the upper-risk level or below the lower risk level as well as how they should apply the CMD exposure minimisation obligation when exposure is between the upper and lower risk levels.

In the German and Dutch risk-based approaches, there is a tripartite agreement on an upper-risk level and a lower risk level at 4:1000 and up to 4: 100 000 respectively over a working life. These risk boundaries might serve as an input for the discussion at EU level.



**Figure 1:** description of the risk-based approach to set OELs for non-threshold carcinogens. With this approach, a predefined upper risk level and lower risk level determine the range of exposure within which the OEL is to be set.

## How many carcinogens with binding OELs do we have so far under the CMD?

Since 1990, when the European Parliament and the Council adopted the first Carcinogens Directive (extended to mutagens in 1999), a total of 25 (groups of) carcinogens have been included in the legal text with binding OELs. All these OELs (except one) were updated or added between 2017 and 2019 with three successive revisions of the CMD (see Table I). Nevertheless, several Member States and the European Trade Unions have called on the European Commission to adopt EU binding OELs for at least 50 priority carcinogens. As this objective endorsed by the former EU Commissioner for Employment has not yet been

achieved, the European Trade Union Confederation (ETUC) insists that binding OEL should be included in the CMD for at least **25 extra** priority carcinogens by 2024.

## Action required on behalf of the European Parliament

Although we welcome the most recent proposal of the European Commission to adopt binding OELs in the CMD for 2 new (group of) carcinogens (**acrylonitrile and nickel compounds**) and to revise the binding OEL for an existing entry (**benzene**) with its fourth revision batch ([COM 2020/571/ final](#)), we still believe that workers in the EU are not adequately protected from work-related cancers and diseases. To improve the protection of the exposed workforce, we demand that the Members of the European Parliament push for:

- the inclusion in the CMD of a new article defining the legal requirements to be used for setting future OELs for carcinogens. The basic principle is that the methodology should be transparent and clearly separate scientific and socio-economic aspects. A high level of protection of workers' health should be guaranteed both for men and women. The level of protection should be homogenous and meet predefined targets for all substances. Socio-economic considerations should be used solely to define a possible transitional period in case of technical feasibility problems with the OEL. To meet these criteria, the legal requirements should:
  - o make a distinction between threshold and non-threshold carcinogens
  - o ensure health-based OELs are set, whenever possible, for threshold carcinogens
  - o ensure a risk-based approach is used to set OELs for non-threshold carcinogens
  - o provide that the risk-based approach ensures a high level of human health protection (in accordance with article 168 of the TFEU)
- the inclusion of the following information for each binding OEL adopted in the CMD Annex III:
  - o whether the OEL is health-based or risk-based
  - o if the OEL is risk-based, the additional cancer risk linked to the numerical value of the OEL. This extra cancer risk should be expressed by the number of workers who would get cancer out of 1000 workers exposed at that level of exposure throughout a working life (8 hours per day, 5 days a week and 40 year-career)
  - o the date of adoption of the OEL and/or its last date of revision
- the inclusion of a mandatory action plan in the employers' risk assessment to make the exposure minimisation obligation transparent for exposed workers and enforcement authorities

- the inclusion in CMD annex I of a new entry to cover Hazardous Medicinal Product in the scope of the Directive (more info can be found in the ETUI specific briefing [here](#) )
- the extension of the CMD scope to substances that are toxic to reproduction (more info can be found in the ETUI specific briefing [here](#) ) and the adoption of binding OELs for [some of them](#).
- the adoption by the European Commission, after consultation of the EU Advisory Committee on Health and Safety, of a multiannual plan making transparent which substances will be prioritised for OEL setting.

## References and further readings

Musu, T. & Vogel, L. 2018. Cancer and work: understanding occupational cancers and taking action to eliminate them. ETUI. <https://www.etui.org/publications/books/cancer-and-work-understanding-occupational-cancers-and-taking-action-to-eliminate-them>

Date of access: 04 Nov 2020.

Wriedt, H. 2016. Carcinogens that should be subject to binding limits on workers exposure. ETUI. <https://www.etui.org/publications/reports/carcinogens-that-should-be-subject-to-binding-limits-on-workers-exposure> Date of access: 04 Nov 2020.

Wriedt, H. 2016. Reprotoxins that should be subject to limit values for workers' exposure. ETUI. <https://www.etui.org/publications/reports/reprotoxins-that-should-be-subject-to-limit-values-for-workers-exposure> Date of access: 04 Nov 2020.

## Annex I: list of carcinogens and corresponding binding OEL in CMD Annex III as of Nov. 2020

In 1997, a binding limit value was set for Benzene in [Dir 97/42/EC](#) and in 1999, binding limit values were set for Hardwood dusts and Vinyl chloride monomer in [Dir 1999/38/EC](#)

	<b>Carcinogens</b>	<b>Binding OEL (8 hours)</b>
1	Benzene*	3.25 mg/m <sup>3</sup>
	Hardwood dusts	reviewed in 2017
	Vinyl chloride monomer	reviewed in 2017

In 2017 binding limit values were reviewed/set for the following agents in [Dir 2017/2398](#)

	<b>Carcinogens</b>	<b>Binding OEL (8 hours)</b>
2	Hardwood dusts	2 mg/m <sup>3</sup> (3 mg/m <sup>3</sup> until 17 Jan 2023)
3	Vinyl chloride monomer	2.6 mg/m <sup>3</sup>
4	Chromium (VI) compounds	0.005 mg/m <sup>3</sup> (0.01 mg/m <sup>3</sup> until 17 Jan 2025) (0.025 mg/m <sup>3</sup> for welding until 17 Jan 2025)
5	Refractory ceramic fibres	0.3 fibres/m <sup>3</sup>
6	Respirable crystalline silica dust	0.1 mg/m <sup>3</sup>
7	Ethylene oxide*	1.8 mg/m <sup>3</sup>
8	1,2-Epoxypropane	2.4 mg/m <sup>3</sup>
9	Acrylamide*	0.1 mg/m <sup>3</sup>
10	2-Nitropropane	18 mg/m <sup>3</sup>
11	1,3-Butadiene	2.2 mg/m <sup>3</sup>
12	o-Toluidine*	0.5 mg/m <sup>3</sup>
13	Hydrazine*	0.013 mg/m <sup>3</sup>
14	Bromoethylene	4.4 mg/m <sup>3</sup>

In early 2019 binding limit values were set for the following agents in [Dir 2019/130](#)

	<b>Carcinogens</b>	<b>Binding OEL (8 hours)</b>
15	Trichloroethylene*	54.7 mg/m <sup>3</sup>
16	4,4'-Methylenedianiline*	0.08 mg/m <sup>3</sup>
17	Epichlorohydrin*	1.9 mg/m <sup>3</sup>
18	Ethylene dibromide*	0.8 mg/m <sup>3</sup>
19	Ethylene dichloride*	8.2 mg/m <sup>3</sup>

20	Diesel engine exhaust emissions	0.05 mg/m <sup>3</sup> from 21 Feb 2023 For underground mining and tunnel construction from 21 Feb 2026
----	---------------------------------	---

In mid-2019 binding limit values were set for the following agents in [Dir 2019/983](#)

	<b>Carcinogens</b>	<b>Binding OEL (8 hours)</b>
21	Cadmium and its inorganic compounds	0.001 mg/m <sup>3</sup> (0.004 mg/m <sup>3</sup> until 11 Jul 2027)
22	Beryllium and inorganic beryllium compounds ##	0.0002 mg/m <sup>3</sup> (0.0006 mg/m <sup>3</sup> until 11 Jul 2026)
23	Arsenic acid and its salts, as well as inorganic arsenic compounds	0.01 mg/m <sup>3</sup> (from 11 Jul 2023 for the copper smelting sector)
24	Formaldehyde #	0.37 mg/m <sup>3</sup> (0.62 mg/m <sup>3</sup> for health care, funeral, and embalming sectors until 11 Jul 2024)
25	4,4'-Methylene-bis (2-chloroaniline) – MOCA*	0.01 mg/m <sup>3</sup>

(\* ) substances with a “skin notation”

(#) dermal sensitisation

(##) dermal and respiratory sensitisation