Annex to Doc. 016-25

Residual risks associated with Binding Occupational Exposure Limit Values of carcinogens under the CMRD (2004/37/EC) and the Asbestos at Work Directive (2009/148/EC).

Introduction

For the majority of carcinogenic substances, it is not possible to identify a safe level of exposure by inhalation at the workplace below which no cancer risk would exist (so-called threshold). For these non-threshold carcinogens, when Binding Occupational Exposure Limit values (BOELs) are set under the Carcinogens, Mutagens and Reprotoxic substances Directive (CMRD), the limit values are still associated with a residual risk.

Many such non-threshold carcinogens can not be eliminated or substituted and minimizing and transparently communicating the remaining risks to workers is therefore regarded necessary.

In line with this, the Advisory Committee on Safety and Health at Work (ACSH) adopted on 30/11/2022 an opinion about the risk-based approach for non-threshold carcinogens (see Doc. 005-22). Within this ACSH opinion the need to communicate transparently the residual risks associated with the BOELs for carcinogens adopted under the CMRD was also agreed on.

The residual risk is defined as the excess lifetime risk of cancer corresponding to a given BOEL based on a scientific assessment of the relationship between a given exposure and the predicted cancer cases (Exposure Risk Relationship, ERR). Residual risks differ from one BOEL to another, inter alia, because socio-economic aspects are taken into account in the process of BOEL setting. The residual risk is expressed as the number of additional cancer cases (additional to the expected number without exposure) that are statistically expected when a cohort of workers are exposed to the substance at an exposure level corresponding to the BOEL throughout their working life (8 hours per day, 5 days per week, 40-years career). In the table below the excess cancer cases is calculated per 1000 workers.

For example, a residual risk of 4:1000 means that, statistically, 4 out of 1000 persons exposed to the substance at the BOEL level throughout a whole working life of 40 years, 40 hours exposure at the week, will develop cancer (additionally to the number of cases that would occur without exposure).

This risk level (4:1000) is a benchmark set in the above-mentioned Advisory Committee on Safety and Health at Work (ACSH) opinion as the “upper risk level”.

In that Opinion the ACSH called for transparent communication of the residual risk, and this is indeed important for several reasons.

First, it makes transparent for everyone that there is still a “residual risk” for employees to develop cancer even in the case of compliance with the BOEL. It is also a tool for employers

to follow progress in the management of carcinogens beyond the compliance with OELs as it provides justification for the obligation to minimise the exposure below the BOEL.

Second, it allows to compare residual risks associated with each BOELs under the CMRD and help ACSH decide which BOEL should be revised in priority to improve worker's protection according to the principles of the ACSH Opinion on the risk-based approach.

The table below gathers available information on residual risks associated with BOELs adopted for carcinogenic substances under the EU Occupational Safety & Health legislation. These residual risks have been estimated by official scientific committees at EU level (Scientific Committee on Occupational Exposure Limits (SCOEL) or Risk Assessment Committee (RAC)). The table reflects the state of knowledge at the time the BOELs and their residual risks were established. For some BOELs in the table no information on residual risks is available from SCOEL or RAC.

In the case of threshold carcinogens (*i.e*. it is possible to identify a safe level of exposure below which there is no adverse effects on exposed workers), there is no number mentioned in the table but rather "no excess risk expected" (in case the adopted BOEL is set at the threshold) or "not calculated at EU level" (in case the adopted BOEL is set above that threshold for socio-economic reasons).

Limit values and associated residuals risks (updated in 15.10.2025)

Chemical agent	**CAS No/ EC No [(1)]**	**Limit value, 8 hours**	**Excess cancer cases /1000 workers [(2)]**	**Reference**
Hardwood dust	-	2 mg/m^3	Not calculated at EU level	SCOEL, 2003
Chromium (VI) compounds	-	0,005 mg/m³	20	SCOEL, 2017
Refractory ceramic fibres	-	0,3 f/ml	Threshold carcinogen with health-based limit value, no excess risk expected	SCOEL, 2011
Respirable crystalline silica	-	0,1 mg/m^3	Not calculated at EU level	SCOEL, 2003
Benzene	71-43-2/ 200-753-7	0,2 ppm (0,66 mg/m^3)	Not calculated at EU level	RAC, 2018
Vinyl chloride monomer	75-01-4/ 200-831-0	1 ppm (2,6 mg/m^3)	0,3	SCOEL, 2004
Ethylene oxide	75-21-8/ 200-849-9	1 ppm (1,8 mg/m^3)	0,1-0,2	SCOEL, 2012
1,2-Epoxypropane	75-56-9/ 200-879-2	1 ppm (2,4 mg/m^3)	Threshold carcinogen with health-based limit value, no excess risk expected	SCOEL, 2010
Trichloroethylene	79-01-6 201-167-4	10 ppm (54,7 mg/m^3)	Threshold carcinogen with health-based	SCOEL, 2009

			limit value, no excess risk expected	
Acrylamide	79-06-1/ 201-173-7	0,1 mg/m^3	Not calculated at EU level (3)	SCOEL, 2012
2-Nitropropane	79-46-9/ 201-209-1	18 mg/m^3 (5 ppm)	28	SCOEL, 2017
o-Toluidine	95-53-4/ 202-429-0	0,5 mg/m^3 (0,1 ppm)	0,24	SCOEL, 2017
4,4'-Methylenedianiline	101-77-9/ 202-974-4	0,08 mg/m^3	Not calculated at EU level (3)	SCOEL, 2012
Epichlorohydrin	106-89-8/ 203-439-8	1,9 mg/m^3	Not calculated at EU level (3)	SCOEL, 2011
Ethylene dibromide	106-93-4/ 203-444-5	0,1 ppm (0,8 mg/m^3)	Not calculated at EU level (3)	SCOEL, 2011
1,3-Butadiene	106-99-0/ 203-450-8	1 ppm (2,2 mg/m^3)	5,4	SCOEL, 2007
Ethylene dichloride	107-06-2/ 203-458-1	2 ppm (8,2 mg/m3)	5,2	SCOEL, 2016
Hydrazine	302-01-2/ 206-114-9	0,013 mg/m^3 (0,01 ppm)	0,17	SCOEL, 2016
Bromoethylene	593-60-2/ 209-800-6	1 ppm (4,4 mg/m^3)	0,9	SCOEL, 2008
Diesel engine exhaust emissions (measured as elemental carbon)	-	0,05 mg/m^3	Not calculated at the EU level (3)	-
Cadmium and its inorganic compounds	-	0,001 mg/m^3	Threshold carcinogen with health-based limit value, no excess risk expected	SCOEL, 2017
Beryllium and inorganic beryllium compounds	-	0,0002 mg/m^3	Threshold carcinogen with health-based limit value, no excess risk expected	SCOEL, 2017
Arsenic acid and its salts, as well as inorganic arsenic compounds	-	0,01 mg/m^3	1,4	RAC, 2017
Formaldehyde	50-00-0/ 200-001-8	0,3 ppm (0,37 mg/m^3)	Threshold carcinogen with health-based limit value, no excess risk expected	SCOEL, 2016
4,4'-Methylene-bis(2-chloroaniline)	101-14-4/ 202-918-9	0,01 mg/m^3	0,1	RAC, 2017
Acrylonitrile	107-13-1/ 203-466-5	1 mg/m^3 (0,45 ppm)	Threshold carcinogen with health-based limit value, no excess risk expected	RAC, 2018

Nickel compounds	-	0,01 mg/m^3 (4) 0,05 mg/m^3 (5)	Not calculated at EU level	RAC, 2018
Asbestos	CAS Nos: 77536-66-4; 12172-73-5; 77536-67-5; 12001-29-5; 12001-28-4; 77536-68-6.	0,01 f/m^3	0,12	RAC, 2021

(1) CAS No: Chemical Abstract Service Registry Number; EC No: Einecs, ELINCS or NLP.
(2) Excess Cancer cases /1000 workers at the EU binding OEL. Assuming exposure over 8 hours per day, 5 days a week and 40-years of working life.
(3) No data available from EU Scientific Committees (SCOEL or RAC). Information from other sources available e.g. in NEG, 2022
(4) Respirable fraction, measured as nickel.
(5) Inhalable fraction, measured as nickel.