

L.N. 102 of 2024

**OCCUPATIONAL HEALTH AND SAFETY AUTHORITY ACT
(CAP. 424)**

**Protection of Workers from the Risks related to Exposure to
Carcinogens or Mutagens at Work (Amendment) Regulations, 2024**

IN EXERCISE of the powers conferred by article 12 of the Occupational Health and Safety Authority Act, the Minister responsible for occupational health and safety, after seeking the advice of the Occupational Health and Safety Authority, has made the following regulations:-

1. The title of these regulations is the Protection of Workers from the Risks related to Exposure to Carcinogens or Mutagens at Work (Amendment) Regulations, 2024, and these regulations shall be read and construed as one with the Protection of Workers from the Risks related to Exposure to Carcinogens or Mutagens at Work Regulations, hereinafter referred to as the "principal regulations".

Citation.

S.L. 424.22.

2. Regulation 1 of the principal regulations shall be amended by the following:

Amends
regulation 1 of
the principal
regulations.

(a) in the title thereof the words "the Risks related to Exposure to Carcinogens or Mutagens" shall be substituted by the words "the Risks related to Exposure to Carcinogens, Mutagens or Reprotoxic Substances";

(b) sub-regulation (2) thereof shall be substituted by the following new sub-regulation:

"(2) These regulations have as their objective the protection of workers against risks to their health and safety, arising from or are likely to result from exposure to carcinogens, mutagens or reprotoxic substances at the workplace, including prevention of such risks.";

(c) sub-regulation (3) thereof shall be substituted by the following new sub-regulation:

"(3) These regulations shall apply to activities in which workers are or are likely to be exposed to carcinogens, mutagens or reprotoxic substances as a result of their work."; and

(d) sub-regulation (6) thereof shall be substituted by the

following new sub-regulation:

"(6) The purpose of these regulations is to transpose:

(a) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC); and

(b) Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014 amending Council Directives 92/58/EEC, 92/85/EEC, 94/33/EC, 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council, in order to align them with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures; and

(c) Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work; and

(d) Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Council Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work; and

(e) Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work; and

(f) Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work."

3. Regulation 2 of the principal regulations shall be amended by the following:

Amends
regulation 2 of
the principal
regulations.

(a) immediately after the definition "Authority" thereof there shall be added the following new definition:

" "biological limit value" means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect";

(b) immediately after paragraph (a) of the definition "carcinogen" thereof there shall be added the following new paragraphs:

"(ba) "reprotoxic substance" means a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;

(bb) "non-threshold reprotoxic substance" means a reprotoxic substance to which there is no safe level of exposure for workers' health and which is identified as such in the notation column of Schedule III;

(bc) "threshold reprotoxic substance" means a reprotoxic substance for which a safe level of exposure exists below which there is no risk to workers' health and which is identified as such in the notation column of Schedule III;"

(c) immediately after the definition "doctor" thereof there shall be added the following new definition:

" "health surveillance" means the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific carcinogens, mutagens or reprotoxic substances at work."; and

(d) the definition "limit value" thereof shall be substituted by the following new definition:

" "limit value" means, unless otherwise specified, the limit of the time-weighted average of the concentration for

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a carcinogen, mutagen or reprotoxic substance in the air within the breathing zone of a worker in relation to a specified reference period as set out in Schedule III;"

Amends
regulation 3 of
the principal
regulations.

4. Regulation 3 of the principal regulations shall be amended by the following:

(a) sub-regulation (1) thereof shall be substituted by the following new sub-regulation:

"(1) In the case of any activity likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens, mutagens or reprotoxic substances. The employer must supply the Authority at its request with the information used for making the assessment."; and

(b) sub-regulation (3) thereof shall be substituted by the following new sub-regulation:

"(3) When the risk assessment is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at particular risk and shall, *inter alia*, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens, mutagens or reprotoxic substances."

Amends
regulation 4 of
the principal
regulations.

5. Sub-regulation (1) of regulation 4 of the principal regulations shall be substituted by the following new sub-regulation:

"(1) The employer shall reduce the use of a carcinogen, mutagen or reprotoxic substance at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be."

Amends
regulation 5 of
the principal
regulations.

6. Sub-regulations (2), (3), (4) and (5) of regulation 5 of the principal regulations shall be substituted by the following new sub-regulations:

"(2) Where it is not technically possible to replace the carcinogen, mutagen or reprotoxic substance by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen, mutagen or reprotoxic substance is, in so far as is technically possible, manufactured and used in a closed system.

(3) Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers to the carcinogen, mutagen or non-threshold reprotoxic substance is reduced to as low a level as is technically possible.

(3A) Where it is not technically possible to use or manufacture a threshold reprotoxic substance in a closed system, the employer shall ensure that the risk related to the exposure of workers to that threshold reprotoxic substance is reduced to a minimum.

(3B) The employer shall, with regard to reprotoxic substances other than non-threshold reprotoxic substances and threshold reprotoxic substances, apply sub-regulation (3A). In such a case, when carrying out the risk assessment referred to in regulation 3, the employer shall duly take into account the possibility that a safe level of exposure for workers' health for such a reprotoxic substance might not exist and shall lay down appropriate measures in that regard.

(4) Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Schedule III.

(5) Wherever a carcinogen, mutagen or reprotoxic substance is used, the employer shall apply all the following measures:

(a) limitation of the quantities of a carcinogen, mutagen or reprotoxic substance at the place of work;

(b) keeping as low as possible the number of workers exposed or likely to be exposed;

(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens, mutagens or reprotoxic substances into the place of work;

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(d) evacuation of carcinogens, mutagens or reprotoxic substances at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;

(e) use of existing appropriate procedures for the measurement of carcinogens, mutagens or reprotoxic substances, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;

(f) application of suitable working procedures and methods;

(g) collective protection measures and, or, where exposure may not be avoided by other means, individual protection measures;

(h) hygiene measures, in particular regular cleaning of floors, walls and other surfaces;

(i) information for workers;

(j) demarcation of risk areas and use of adequate warning and safety signs including "no smoking" signs in areas where workers are exposed or likely to be exposed to carcinogens, mutagens or reprotoxic substances;

(k) drawing up plans to deal with emergencies likely to result in abnormally high exposure;

(l) means for safe storage, handling and transportation, in particular by using sealed and clearly and visibly labelled containers;

(m) means for safe collection, storage and disposal of waste by workers, including the use of sealed and clearly and visibly labelled containers."

Amends
regulation 6 of
the principal
regulation.

7. Paragraphs (a) and (b) of regulation 6 of the principal regulations, shall be substituted by the following:

"(a) the activities and, or industrial processes carried out, including the reasons for which carcinogens, mutagens or reprotoxic substances are used;

(b) the quantities of substances or mixtures manufactured

or used which contain carcinogens, mutagens or reprotoxic substances;".

8. Sub-regulation (1) of regulation 10 of the principal regulations shall be amended by the following:

Amends regulation 10 of the principal regulations.

(a) the words "Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens or mutagens, to take appropriate measures to ensure that" thereof shall be substituted by the words "Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, mutagens or reprotoxic substances, to take appropriate measures to ensure that:"; and

(b) paragraph (a) thereof shall be substituted by the following new paragraph:

"(a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens or reprotoxic substances;".

9. Regulation 11 of the principal regulations shall be amended by the following:

Amends regulation 11 of the principal regulations.

(a) in sub-regulation (1) thereof the words "The training shall be:

- adapted to take account of new or changed risk, and

- repeated periodically if necessary." shall be substituted by the words:

"The training shall be:

(i) adapted to take account of new or changed risk, in particular when workers are or likely to be exposed to new carcinogens, mutagens or reprotoxic substances or to a number of different carcinogens, mutagens or reprotoxic substances, including those contained in hazardous medicinal products, or in case of changing circumstances related to work,

(ii) provided periodically in healthcare settings to all workers who are exposed to carcinogens, mutagens or reprotoxic substances, in particular where new hazardous medicinal products containing those substances are used, and

(iii) repeated periodically in other settings if necessary."; and

(b) sub-regulation (2) thereof shall be substituted by the following new sub-regulation:

"(2) Employers shall inform workers of installations and related containers containing carcinogens, mutagens or reprotoxic substances, ensure that all containers, packages and installations containing carcinogens, mutagens or reprotoxic substances are labelled clearly and legibly, and display clearly visible warning and hazard signs.

Where a biological limit value has been set out in Schedule IV, health surveillance shall be mandatory for working with the carcinogen, mutagen or reprotoxic substance in question, in accordance with the procedures laid down in that Schedule. Workers shall be informed of that requirement before being assigned to the task involving the risk of exposure to the carcinogen, mutagen or reprotoxic substance indicated."

Amends
regulation 14 of
the principal
regulations.

10. Regulation 14 of the principal regulations shall be amended by the following:

(a) sub-regulation (3) and (4) thereof shall be substituted by the following new sub-regulations:

"(3) If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, mutagens or reprotoxic substances, or if a biological limit value is found to have been exceeded, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

(4) In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual workers. Biological monitoring and related requirements may form part of health surveillance."; and

(b) sub-regulation (8) thereof shall be substituted by the following new regulation:

"(8) All cases of cancer, adverse effects on sexual

function and fertility in adult male and female workers or developmental toxicity in their offspring identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen, mutagen or reprotoxic substance shall be notified to the competent authority."

11. Sub-regulation (1) of regulation 15 of the principal regulations, shall be substituted by the following new sub-regulations:

Amends regulation 15 of the principal regulations.

"(1) With regard to carcinogens and mutagens, the list referred to in paragraph (c) of regulation 12, and the medical record referred to in regulation 14(4) shall be kept for at least forty (40) years following the end of exposure, in accordance with national law or practice.

(1A). With regard to reprotoxic substances, the list referred to in paragraph (c) of regulation 12, and the medical record referred to in regulation 14(4) shall be kept for at least five (5) years following the end of exposure, in accordance with national law or practice."

12. Item 1 of Schedule II to the principal regulations shall be substituted by the following new item:

Amends Schedule II to the principal regulations.

"1. The doctor and, or authority responsible for the health surveillance of workers exposed to carcinogens, mutagens or reprotoxic substances shall be familiar with the exposure conditions or circumstances of each worker."

13. Schedule III to principal regulations shall be substituted by the following new Schedule:

Substitutes Schedule III to the principal regulations.

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Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m ³ (5)	ppm (6)	f/ml (7)	mg/m ³ (5)	ppm (6)	f/ml (7)		
Hardwood dusts	-	-	2 (8)	-	-	-	-	-	-	Limit value: 3 mg/m ³ until 17 January 2023

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<p>Chromium (VI) compounds which are carcinogens within the meaning of paragraph (a) of the definition "carcinogen" in regulation 2 (as chromium)</p>		<p>0.005</p>					<p>Limit value: 0.010 mg/m³ until 17 January 2025 Limit value: 0.025 mg/m³ for welding or plasma cutting processes or similar work processes that generate fume until 17 January 2025</p>
<p>Refractory ceramic fibres which are carcinogens within the meaning of paragraph (a) of definition "carcinogen" in regulation 2</p>				<p>0.3</p>			
<p>Respirable crystalline silica dust</p>		<p>0.1 ⁽⁹⁾</p>					

Benzene	200-753-7	71-43-2	0.66	0.2	-	-	-	-	skin (10)	Limit value of 1ppm (3.25 mg/m ³) until 5 April 2024. Limit value of 0,5 ppm (1.65 mg/m ³) from 5 April 2024 until 5 April 2026.
Vinyl chloride monomer	200-831-0	75-01-4	2.6	1	-	-	-	-	-	-
Ethylene oxide	200-849-9	75-21-8	1.8	1	-	-	-	-	skin (10)	-
1,2- Epoxypropane	200-879-2	75-56-9	2.4	1	-	-	-	-	-	-
Trichloroethylene	201-167-4	79-01-6	54.7	10	-	164	30	-	skin (10)	-
Acrylamide	201-173-7	79-06-1	0.1	-	-	-	-	-	skin (10)	-
2-Nitropropane	201-209-1	79-46-9	18	5	-	-	-	-	-	-
o-Toluidine	202-429-0	95-53-4	0.5	0.1	-	-	-	-	skin (10)	-
4,4'-Methylenedianiline	202-974-4	101-77-9	0.08	-	-	-	-	-	skin (10)	-
Epichlorohydrine	203-439-8	106-89-8	1.9	-	-	-	-	-	skin (10)	-
Ethylene dibromide	203-444-5	106-93-4	0.8	0.1	-	-	-	-	skin (10)	-
1,3-Butadiene	203-450-8	106-99-0	2.2	1	-	-	-	-	-	-
Ethylene dichloride	203-458-1	107-06-2	8.2	2	-	-	-	-	skin (10)	-
Hydrazine	206-114-9	302-01-2	0.013	0.01	-	-	-	-	skin (10)	-
Bromoethylene	209-800-6	593-60-2	4.4	1	-	-	-	-	-	-

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Diesel engine exhaust emissions	-	-	0.05 ^(*)	-	-	-	-	-	-	The limit value shall apply from 21 February 2023. For underground mining and tunnel construction the limit value shall apply from 21 February 2026.
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of these regulations	-	-	-	-	-	-	-	-	skin (10)	-
Mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine	-	-	-	-	-	-	-	-	skin (10)	-
Cadmium and its inorganic compounds	-	-	0.001 ⁽¹¹⁾	-	-	-	-	-	-	Limit value: 0.004 mg/m ³ ⁽¹²⁾ until 11 July 2027

Beryllium and inorganic beryllium compounds	-	-	0.0002 ⁽¹¹⁾	-	-	-	-	-	dermal and respiratory sensitisation ⁽¹³⁾	Limit value: 0.0006 mg/m ³ until 11 July 2026
Arsenic acid and its salts, as well as inorganic arsenic compounds	-	-	0.01 ⁽¹¹⁾	-	-	-	-	-	-	For the copper smelting sector, the limit value shall apply from 11 July 2023
Formaldehyde	200-001-8	50-00-0	0.37	0.3	-	0.7	0.6	-	dermal sensitisation ⁽¹⁴⁾	Limit value: 0.62 mg/m ³ or 0.5 ppm ⁽³⁾ for the health care, funeral and embalming sectors until 11 July 2024
4,4'-Methylene-bis(2-chloroaniline)	202-918-9	101-14-4	0.01	-	-	-	-	-	skin ⁽¹⁰⁾	
Acrylonitrile	203-466-5	107-13-1	1	0.45	-	4	1.8	-	Skin ⁽¹⁰⁾ Dermal sensitisation ⁽¹⁴⁾	The limit values shall apply from 5 April 2026.

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Nickel compounds	-	-	0.01 ⁽¹⁵⁾ 0.05 ⁽¹⁶⁾	-	-	-	-	-	Dermal and respiratory sensitisation ⁽¹³⁾	The limit value ⁽¹⁵⁾ shall apply from 18 January 2025. The limit value ⁽¹⁶⁾ shall apply from 18 January 2025. Until then a limit value of 0.1 mg/m ³ ⁽¹⁶⁾ shall apply.
Inorganic lead and its compounds	-	-	0.15	-	-	-	-	-	-	-
N,N-dimethylacetamide	204-826-4	127-19-5	36	10	-	72	20	-	Skin ⁽¹⁰⁾	-
Nitrobenzene	202-716-0	98-95-3	1	0.2	-	-	-	-	Skin ⁽¹⁰⁾	-
N,N-Dimethylformamide	200-679-5	68-12-2	15	5	-	30	10	-	Skin ⁽¹⁰⁾	-
2-Methoxyethanol	203-713-7	109-86-4	-	1	-	-	-	-	Skin ⁽¹⁰⁾	-
2-Methoxyethyl acetate	203-772-9	110-49-6	-	1	-	-	-	-	Skin ⁽¹⁰⁾	-
2-Ethoxyethanol	203-804-1	110-80-5	8	2	-	-	-	-	Skin ⁽¹⁰⁾	-
2-Ethoxyethyl acetate	203-839-2	111-15-9	11	2	-	-	-	-	Skin ⁽¹⁰⁾	-

1-Methyl-2-pyrrolidone	212-828-1	872-50-4	40	10	-	80	20	-	Skin (¹⁰)	-
Mercury and divalent inorganic mercury compounds including mercury oxide and mercury chloride (measured as mercury)	-	-	0.02	-	-	-	-	-	-	-
Bisphenol A; 4,4'-Isopropylidenediphenol	201-245-8	80-05-7	2 (¹¹)	-	-	-	-	-	-	-
Carbon monoxide	211-128-3	630-08-0	23	20	-	117	100	-	-	-

- (1) EC No, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, of Regulation (EC) No 1272/2008.
- (2) CAS No: Chemical Abstract Service Registry Number.
- (3) Measured or calculated in relation to a reference period of eight (8) hours time-weighted average (TWA)
- (4) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
- (5) mg/m³ = milligrams per cubic metre of air at 20 °C and 101.3 kPa (760 mm mercury pressure).
- (6) ppm = parts per million by volume in air (ml/m³).
- (7) f/ml = fibres per millilitre.
- (8) Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.
- (9) Respirable fraction.
- (10) Substantial contribution to the total body burden via possible dermal exposure
- (11) Inhalable fraction
- (12) Inhalable fraction. Respirable fraction in those Member States that implement, on the date of the entry into force of this Directive, a monitoring system with a biological limit value not exceeding 0.002 mg Cd/g creatinine in urine.
- (13) The substance can cause sensitisation of the skin and of the respiratory tract.
- (14) The substance can cause sensitisation of the skin.
- (15) Respirable fraction, measured as nickel.
- (16) Inhalable fraction, measured as nickel.
- (*) Measured as elemental carbon.

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Adds new
Schedule IV to
the principal
regulations.

14. Immediately after Schedule III to the principal regulations there shall be added the following new Schedule IV:

"SCHEDULE IV
BIOLOGICAL LIMIT VALUES AND HEALTH
SURVEILLANCE MEASURES
(Regulation 16(3))

1. Lead and its ionic compounds

Biological monitoring shall include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:

70 µg Pb/100 ml blood

Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0.075 mg/m³,

calculated as a time-weighted average over forty (40) hours per week, or a blood-lead level greater than 40 $\mu\text{g Pb}/100\text{ ml}$ blood is measured in individual workers."

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