

**L.N. 122 of 2003**

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

**Regulations on the protection of workers from the risks related to  
exposure to carcinogens or mutagens at work, 2003**

IN EXERCISE of the powers conferred by article 12 of the Occupational Health and Safety Act, the Deputy Prime Minister and Minister for Social Policy, in consultation with the Occupational Health and Safety Authority, has made the following regulations:-

Citation, scope and application.

**1.** (1) The title of these regulations is the Regulations on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, 2003.

(2) These regulations aim to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, and lay down minimum requirements in this area, including limit values.

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

(4) As regards asbestos, insofar as any provisions in these Regulations are more favourable to safety and health at work than any other provision contained in regulations dealing with asbestos, these regulations shall apply.

(5) These Regulations shall not apply to workers exposed only to radiation insofar as such issue is regulated under any other regulation or legislative provision.

Interpretation.

**2.** In these regulations, unless the context otherwise requires:

“Act” means the Occupational Health and Safety Authority Act; Cap. 424

“Authority” means the Occupational Health and Safety Authority established by article 8 of the Act;

“carcinogen” means:

(i) a substance which meets the criteria for classification as a category 1 or 2 carcinogen set out in Annex VI of Directive 67/548/EEC;

(ii) a preparation composed of one or more substances referred to in point (i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 carcinogen set out either:

- in Annex I to Directive 67/548/EEC, or
- in Annex I to Directive 88/379/EEC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

(iii) a substance, preparation or process referred to in Annex I as well as a substance or preparation released by a process referred to in Annex I;

“doctor” means a medical practitioner, specialised in internal or oncological medicine, who is appointed by an employer to examine workers exposed to carcinogens or mutagens;

“limit value” means, unless otherwise specified, the limit of the time-weighted average of the concentration for a “carcinogen or mutagen” in the air within the breathing zone of a worker in relation to a specified period as set out in Schedule III;

“mutagen” means:

(i) a substance which meets the criteria for classification as a category 1 or 2 mutagen set out in Annex VI to Directive 67/548/EEC;

(ii) a preparation composed of one or more substances referred to in (i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 mutagen set out in either:

- Annex I to Directive 67/548/EEC, or
- Annex I to Directive 88/379/EEC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

Determination of risks.

**3.** (1) In the case of any activity likely to involve a risk of exposure to carcinogens or mutagens, the nature, degree and duration of workers' exposure must 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 must be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens or mutagens.

The employer must supply the Authority at its request with the information used for making the assessment.

(2) When assessing the risk, account shall be taken of all other routes of exposure, such as absorption into and/or through the skin.

(3) When the assessment referred to in this regulation is carried out, an employer 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 or mutagens.

Reduction and replacement.

**4.** (1) The employer shall reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, preparation 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.

(2) The employer shall, upon request, submit the findings of his investigations to the Authority.

Prevention and reduction of exposure.

**5.** (1) Where the results of the assessment referred to in regulation 3 reveal a risk to workers' health or safety, workers' exposure must be prevented.

(2) Where it is not technically possible to replace the carcinogen or mutagen by a substance, preparation 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 or the mutagen 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 is reduced to as low a level as is technically possible.

(4) Exposure shall not exceed the limit values as set out in Schedule III

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

(a) limitation of the quantities of a carcinogen or mutagen 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 minimize the release of carcinogens or mutagens into the place of work;

(d) evacuation of carcinogens or mutagens 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 or mutagens, 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 cannot 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 or mutagens;

(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.

Information for the Authority.

**6.** Where the results of the assessment referred to in regulation 3 reveal a risk to workers' health or safety, an employer shall, when requested, make available to the Authority appropriate information on:

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

(b) the quantities of substances or preparations manufactured or used which contain carcinogens or mutagens;

(c) the number of workers exposed;

(d) the preventive measures taken;

(e) the type of protective equipment used;

(f) the nature and degree of exposure;

(g) the cases of replacement.

**7.** (1) In the event of an unforeseeable event or an accident which is likely to result in an abnormal exposure of workers, the employer shall inform the workers thereof. Unforeseen exposure

(2) Until the situation has been restored to normal and the causes of the abnormal exposure have been eliminated:

(a) only those workers who are essential to the carrying out of repairs and other necessary work shall be permitted to work in the affected area;

(b) the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear; the exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker;

(c) unprotected workers shall not be allowed to work in the affected area.

Foreseeable exposure.

**8.** (1) For certain activities such as maintenance, in respect of which it is foreseeable that there is the potential for a significant increase in exposure of workers, and in respect of which all scope for further technical preventive measures for limiting workers' exposure has already

been exhausted, the employer shall determine, after consultation of the workers and/or their representatives in the undertaking or establishment, without prejudice to the employer's responsibility, the measures necessary to reduce the duration of workers' exposure to the minimum possible and to ensure protection of workers while they are engaged in such activities.

(2) Pursuant to the first sub-article (1), the workers concerned shall be provided with protective clothing and individual respiratory protection equipment which they must wear as long as the abnormal exposure persists; that exposure may not be permanent and shall be kept to the strict minimum of time necessary for each worker.

(3) Appropriate measures shall be taken to ensure that the areas in which the activities referred to in the sub-article (1) take place are clearly demarcated and indicated or that unauthorized persons are prevented by other means from having access to such areas.

**9.** Appropriate measures shall be taken by employers to ensure that access to areas in which the activities in respect of which the results of the assessment referred to in regulation 3 reveal a risk to workers' safety or health take place are accessible solely to workers who, by reason of their work or duties, are required to enter them. Access to risk areas

**10.** (1) 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: Personal hygiene and individual protection

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

(b) workers are provided with appropriate protective clothing or other appropriate special clothing;

(c) separate storage places are provided for working or protective clothing and for street clothes;

(d) workers are provided with appropriate and adequate washing and toilet facilities;

(e) protective equipment is properly stored in a well-defined place; it is checked and cleaned if possible before, and in any case after, each use; defective equipment is repaired or replaced before further use.

(2) Workers may not be charged for the cost of these measures.

Information and training of workers.

**11.** (1) Appropriate measures shall be taken by the employer to ensure that workers and, or workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:

- (a) potential risks to health, including the additional risks due to tobacco consumption;
- (b) precautions to be taken to prevent exposure;
- (c) hygiene requirements;
- (d) wearing and use of protective equipment and clothing;
- (e) steps to be taken by workers, including rescue workers, in the case of incidents and to prevent incidents.

The training shall be:

- adapted to take account of new or changed risk, and
- repeated periodically if necessary.

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

Information for workers.

**12.** Appropriate measures shall be taken to ensure that:

(a) workers and, or any workers' representatives in the undertaking or establishment can check that these Regulations are applied or can be involved in its application, in particular with regard to:

- (i) the consequences for workers' safety and health of the selection, wearing and use of protective clothing and equipment, without prejudice to the employer's responsibility for determining the effectiveness of protective clothing and equipment;

(ii) the measures determined by the employer which are referred to in the first sub-paragraph of regulation 8(1), without prejudice to the employer's responsibility for determining such measures;

(b) workers and, or any workers' representatives in the undertaking or establishment are informed as quickly as possible of abnormal exposures, including those referred to in regulation 8, of the causes thereof and of the measures taken or to be taken to rectify the situation;

(c) the employer keeps an up-to-date list of the workers engaged in the activities in respect of which the results of the assessment referred to in regulation 3 reveal a risk to workers' health or safety, indicating, if the information is available, the exposure to which they have been subjected;

(d) the doctor and, or the Authority as well as all other persons who have responsibility for health and safety at work at the employer's workplace have access to the list referred to in subparagraph (c);

(e) each worker has access to the information on the list which relates to him personally;

(f) workers and, or any workers' representatives in the undertaking or establishment have access to anonymous collective information.

**13.** (1) Employers shall consult workers and, or their representatives and allow them to take part in discussions on all questions relating to safety and health at work. This presupposes:

Consultation and participation of workers.

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- the consultation of workers,
- the right of workers and/or their representatives to make proposals,
- balanced participation in accordance with the General Provisions for Health and Safety at Work Places Regulations, 2003.

(2) Workers or workers' representatives with specific responsibility for the safety and health of workers shall take part in a balanced way, in accordance with applicable laws and/or practices, and shall be consulted in advance and in good time by the employer with regard to:

(a) any measure which may substantially affect safety and health;

(b) the designation of worker or workers which the employer is obliged to designate to carry out activities related to the protection and prevention of occupational risks for the undertaking and/or establishment and the workers which the employer is obliged to designate to implement measures inter alia, for first aid, fire-fighting and the evacuation of workers, and the activities related to the protection and prevention of occupational risks;

(c) the following information:

(i) an assessment of the risks to safety and health at work, including those facing groups of workers exposed to particular risks;

(ii) the protective measures to be taken and, if necessary, the protective equipment to be used;

(iii) a list of occupational accidents resulting in a worker being unfit for work for more than three working days;

(iv) reports on occupational accidents suffered by his workers;

(v) the safety and health risks and protective and preventive measures and activities in respect of both the undertaking and/or establishment in general and each type of workstation and, or job;

(vi) the measures taken in relation to first aid, fire-fighting and the evacuation of workers.

(vii) the appropriate measures taken so that employers of workers from any outside undertakings and/or establishments engaged in work in his undertaking and, or establishment receive adequate information concerning the points referred to in sub-paragraphs (v) and (vi).

(viii) the appropriate measures taken so that workers with specific functions in protecting the safety and health of workers, or workers' representatives with specific responsibility for the safety and health of workers may be able to have access, to carry out their functions and to:

- the risk assessment and protective measures referred to in sub-paragraphs (v) and (vi) above;
- the list and reports referred to in sub-paragraphs (iii) and (iv) above;
- the information yielded by protective and preventive measures, inspection agencies and bodies responsible for safety and health.

(d) the enlistment, where appropriate, of the competent services or persons outside the undertaking and, or establishment, where such protective and preventive measures cannot be organized for lack of competent personnel in the undertaking and/or establishment;

(e) the planning and organization of the training to each worker regarding adequate safety and health training, in particular in the form of information and instructions specific to his workstation or job:

- on recruitment,
- in the event of a transfer or a change of job,
- in the event of the introduction of new work equipment or a change in equipment,
- in the event of the introduction of any new technology.

(3) Workers' representatives with specific responsibility for the safety and health of workers shall have the right to ask the employer to take appropriate measures and to submit proposals to him to that end to mitigate hazards for workers and/or to remove sources of danger.

(4) The workers referred to in paragraph (2) and the workers' representatives referred to in paragraphs (2) and (3) may not be placed at a disadvantage because of their respective activities referred to in paragraphs (2) and (3).

(5) Employers must allow workers' representatives with specific responsibility for the safety and health of workers adequate time off work, without loss of pay, and provide them with the necessary means to enable such representatives to exercise their rights and functions.

(6) Workers and/or their representatives are entitled to appeal to the Authority if they consider that the measures taken and the means employed by the employer are inadequate for the purposes of

ensuring safety and health at work. Workers' representatives must be given the opportunity to submit their observations during inspection visits by the Authority.

Health surveillance.

**14.** (1) The employer shall make arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in regulation 3 reveal a risk to health or safety.

(2) The arrangements referred to in paragraph (1) shall be such that each worker shall be able to undergo, if appropriate, relevant health surveillance:

- prior to exposure,
- at regular intervals thereafter.

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

(3) If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens or mutagens, the doctor or the Authority may require other workers who have been similarly exposed to undergo health surveillance. In that event, a reassessment of the risk of exposure shall be carried out in accordance with regulation 3.

(4) In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or the Authority shall propose any protective or preventive measures to be taken in respect of any individual workers.

(5) Information and advice must be given to workers regarding any health surveillance which they may undergo following the end of exposure.

(6) Workers shall have access to the results of the health surveillance which concern them, and the workers concerned or the employer may request a review of the results of the health surveillance.

(7) Practical recommendations for the health surveillance of workers are given in Schedule II.

(8) All cases of cancer identified in accordance with applicable laws and, or practice as resulting from occupational exposure to a carcinogen or mutagen shall be notified to the Authority.

**15.** (1) The list referred to in regulation 12 (c) and the medical records referred to in regulation 14(4) shall be kept for at least 40 years following the end of exposure. Record keeping.

(2) Those documents shall be made available to the Authority in cases where the undertaking ceases activity.

**16.** Limit values and other directly related provisions are set out in Schedule III. Limit values.

**17.** In any proceedings for an offence under these regulations consisting of a failure to comply with a duty or requirement to do something, or to do something so far as is reasonably practicable, it shall be for the accused to prove (as the case may be) that it was not practicable or not reasonably practicable to do more than was in fact done to satisfy the duty or requirement, or that there was no better practicable means than was in fact used to satisfy the duty or requirement. Onus of proof.

**18.** Any person who knowingly or recklessly interferes with the process of providing a safe and healthy place of work, shall be guilty of an offence. Offences.

## **SCHEDULE I**

### **List of substances, preparations and processes (Regulation 2 (c))**

1. Manufacture of auramine.
2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soots, coal tar or coal pitch.
3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes.
4. Strong acid process in the manufacture of isopropyl alcohol.
5. Work involving exposure to hardwood dust.

## **SCHEDULE II**

### **Practical recommendations for the health surveillance of workers (Regulation 14 (7))**

1. The doctor must be familiar with the exposure conditions or circumstances of each worker.

2. Health monitoring of workers must be carried out in accordance with the principles and practices of occupational medicine; it must include at least the following measures:

- keeping records of a worker's medical and occupational history,
- a personal interview,
- where appropriate, biological monitoring, as well as detection of early and reversible effects.

Further tests may be decided upon for each worker when he is the subject of health monitoring, in the light of the most recent knowledge available to occupational medicine.

### SCHEDULE III

#### Limit values and other directly related provisions (Regulation 16)

##### A. Limit values for occupational exposure

Name of agent	EINECS <sup>(1)</sup>	CAS <sup>(2)</sup>	Limit values		Notation
			mg/m <sup>3</sup> <sup>(3)</sup>	ppm <sup>(4)</sup>	
Benzene	200-753-7	71-43-2	3.25 <sup>(5)</sup>	1 <sup>(5)</sup>	Skin <sup>(6)</sup>
Vinyl chloride monomer	200-831		75-01-4	7.77 <sup>(5)</sup>	3 <sup>(5)</sup> -
Trab ta' injam <i>hardwood</i>	-	-	5.0 <sup>(5)</sup> <sup>(7)</sup>	-	-

(1) EINECSĠ European Inventory of Existing Chemical Substances.  
 (2) CASĠ Chemical Abstract service Number.  
 (3) mgċm<sup>3</sup> = milligrams per cubic metre of air at 20 ∞ C and 101.3kPa (760 mm mercury pressure).  
 (4) ppm = parts per million by volume in air (mlċm<sup>3</sup>).  
 (5) Measured or caluclated in relation to a reference period of eight hours.  
 (6) Substantial contribution to the total body burden via dermal exposure possible.  
 (7) Inhalable fractionġ if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture.