STATUTORY INSTRUMENTS.

S.I. No. 122 of 2024

SAFETY, HEALTH AND WELFARE AT WORK (CARCINOGENS, MUTAGENS AND REPROTOXIC SUBSTANCES) REGULATIONS 2024

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I, NEALE RICHMOND, Minister of State at the Department of Enterprise, Trade and Employment, in exercise of the powers conferred on me by section 58 of the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005) (as adapted by the Business, Enterprise and Innovation (Alteration of Name of Department and Title of Minister) Order 2020 (S.I. No. 519 of 2020)) and the Enterprise, Trade and Employment (Delegation of Ministerial Functions) Order 2023 (No. 14 of 2023), and for the purpose of giving effect to Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022[1] amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work[2], and after consultation with the Health and Safety Authority, hereby make the following regulations:

Citation and commencement

1. (1) These Regulations may be cited as the Safety, Health and Welfare at Work (Carcinogens, Mutagens and Reprotoxic Substances) Regulations 2024.

(2) These Regulations come into operation on 5 April 2024.

Interpretation

2. (1) In these Regulations—

"Act of 2005" means the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005);

"Authority" means the Health and Safety Authority;

"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, as set out in the Code of Practice;

"carcinogen" means—

(a) a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No. 1272/2008 of the European Parliament and of the Council[3], or

(b) a substance, mixture or process referred to in the Code of Practice as well as a substance or mixture released by a process referred to in that Code of Practice;

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[1] OJ No. L 88, 16.3.2022, p. 1.
[2] OJ No. L 158, 30.4.2004, p. 50.
[3] OJ No. L 353, 31.12.2008, p. 1.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 29*th March*, 2024.

"Code of Practice" means, for the purposes of these Regulations, a code of practice prepared and published under section 60 of the Act of 2005, including part of such code, and refers to the latest edition published;

"Directive" means Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004[4], as amended by Article 5 of Directive 2014/27/EU of the European Parliament and of the Council of 26 February 2014[5], Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017[6], Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019[7], Directive (EU) 2019/983 of the European Parliament and of the Council of 5 June 2019[8] and Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022[9];

"employer" has the meaning attached to it in the Act of 2005;

"health surveillance" means the assessment of an individual employee to determine the state of health of that individual, as related to exposure to specific carcinogens, mutagens or reprotoxic substances at work and includes biological monitoring, so that any adverse variations in their health which may be related to working conditions are identified as early as possible;

"limit value" means, unless otherwise specified, the limit of the time-weighted average of the concentration for a carcinogen, mutagen or reprotoxic substance in the air within the breathing zone of an employee in relation to a specified reference period as set out in the Code of Practice;

"mutagen" means a substance or mixture which meets the criteria for classification as a category 1A or 1B germ cell mutagen set out in Annex I to Regulation (EC) No. 1272/2008;

"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, and may be grouped as follows:

(a) "non-threshold reprotoxic substances" for which there is no safe level of exposure for employees' health, and which is identified as such in the Code of Practice; or

(b) "threshold reprotoxic substances" for which a safe level of exposure exists below which there is no risk to employees' health, and which is identified as such in the Code of Practice;

"responsible medical practitioner" means the practitioner employed, or otherwise engaged, by an employer to be responsible for health surveillance of employees covered by these Regulations, and may include:

(a) a registered medical practitioner whose name is entered in the General Register of Medical Practitioners;

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[4] OJ No. L 158, 30.4.2004, p. 50.
[5] OJ No. L 65, 5.3.2014, p. 1.
[6] OJ No. L 345, 27.12.2017, p. 87.
[7] OJ No. L 30, 31.1.2019, p. 112.
[8] OJ No. L 164, 20.6.2019, p. 23.
[9] OJ No. L 88, 16.3.2022, p. 1.

(b) a general practitioner;

(c) a registered nurse;

(d) a consultant doctor;

(e) an occupational healthcare professional or other suitable qualified person employed, or otherwise engaged, by an employer to be responsible for health surveillance of employees covered by these Regulations; and

(f) an occupational medical adviser designated under section 63 of the Act of 2005;

"safety representative" has the meaning attached to it in the Act of 2005.

(2) A word or expression which is used in these Regulations and which is also used in the Directive has, unless the contrary intention appears, the same meaning in these Regulations as it has in the Directive.

Application

3. (1) These Regulations apply where carcinogens, mutagens or reprotoxic substances are present or may be present at the workplace.

(2) These Regulations apply to a self-employed person as they apply to an employer and as if that self-employed person was an employer and his own employee.

(3) These Regulations apply to an employer in respect of the use by them of the services of a fixed-term employee or a temporary employee, taking into account the provisions of section 8(3) of the Act of 2005.

(4) Where duties, however expressed, are placed by these Regulations on an employer in respect of any of their employees at a workplace, a like duty applies in respect of every other person at work at that workplace who is or may be exposed at that place to a carcinogen, mutagen or reprotoxic substance as defined in Regulation 2(1), except that the duties under Regulations 11 and 12 shall not apply to a person who is not their employee.

(5) Obligations and duties arising under these Regulations are in addition to obligations and duties arising under any other enactment.

(6) As regards asbestos, these Regulations shall apply in addition to the Safety, Health and Welfare at Work (Exposure to Asbestos) Regulations 2006 and 2010, where such application is more favourable to health and safety at work.

General duties of employer

4. (1) The employer shall determine whether any carcinogens, mutagens or reprotoxic substances are present or may be present at the workplace.

(2) The employer shall engage a competent person to assess any risk to the health or safety of employees who are, or are likely to be, exposed to

carcinogens, mutagens or reprotoxic substances as a result of their work. The risk assessment shall:

(a) take account of the nature, degree and duration of exposure;

(b) be renewed regularly and whenever any change occurs in conditions which may affect an employee's exposure to carcinogens, mutagens or reprotoxic substances;

(c) take account of all other routes of exposure to carcinogens, mutagens or reprotoxic substances, including absorption either into or through the skin or both; and

(d) give particular attention to any effects concerning the health or safety of employees at particular risk and to take account of the desirability of not having such employees present in areas where they may be exposed to carcinogens, mutagens or reprotoxic substances.

(3) Where the results of the assessment required by paragraph (2) reveal a risk to employees' health or safety, the employer shall prevent exposure.

(4) In the case of any area where an assessment under paragraph (2) reveals a risk to employees' health or safety, access should be restricted only to those employees who must enter in order to perform their work or duties.

(5) Every employer shall reduce the use of a carcinogen, mutagen or reprotoxic substance at the workplace, 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 an employee's health or safety.

(6) Wherever 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.

(7) Wherever a closed system is not technically possible, the employer shall—

(a) with regard to a carcinogen, mutagen or non-threshold reprotoxic substance, ensure that the level of exposure of employees is reduced to as low a level as is technically possible,

(b) with regard to a threshold reprotoxic substance, ensure that the risk related to the exposure of employees is reduced to a minimum, or

(c) with regard to reprotoxic substances other than non-threshold reprotoxic substances and threshold reprotoxic substances, ensure that the risk related to the exposure of employees is reduced to a minimum. In such a case, when carrying out the risk assessment required by paragraph (2) of this Regulation, the employer shall consider the possibility that a safe level of

exposure for such a reprotoxic substance might not exist and shall lay down appropriate measures in that regard.

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

(a) limit the quantities of the carcinogen, mutagen or reprotoxic substance;

(b) minimise the number of employees exposed or likely to be exposed to the carcinogen, mutagen or reprotoxic substance;

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

(d) use appropriate systems for the extraction of carcinogens, mutagens or reprotoxic substances at source, all such systems to be compatible with the need to protect health and the environment;

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

(f) use suitable working procedures and methods;

(g) use collective protection measures and where exposure cannot be avoided by other means, individual protection measures;

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

(i) provide information for employees;

(j) demarcate risk areas and use adequate warning and safety signs, including “no smoking” signs, in areas where employees are exposed or are likely to be exposed to carcinogens, mutagens or reprotoxic substances;

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

(l) ensure the safe storage, handling and transportation of all containers, packages and installations containing carcinogens, mutagens or reprotoxic substances, in particular by using sealed containers which are labelled clearly and legibly and which display clearly visible warning and hazard signs; and

(m) ensure the safe collection, storage and disposal of carcinogenic, mutagenic or reprotoxic substance waste by employees, including the use of sealed containers which are labelled clearly and legibly.

(9) The employer shall ensure that exposure does not exceed either—

(a) the limit value of a carcinogen, mutagen or reprotoxic substance set by the Authority in the Code of Practice, or

(b) a biological limit value set by the Authority in the Code of Practice.

(10) Where a biological limit value has been set by the Authority in the Code of Practice, the employer shall inform employees, before assigning them to a task involving the risk of exposure, that health surveillance shall be mandatory, unless otherwise stated in the Code of Practice, for employees exposed to the substance in question. Such health surveillance should be carried out in accordance with the procedures laid down in Regulation 11 and in the Code of Practice.

Information made available to the Authority

5. (1) The employer shall provide the Authority at their request with all information used for making the assessment required by Regulation 4(2), and the findings of any such assessment, including:

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

(b) the quantities of substances or mixtures manufactured, generated or used which contain carcinogens, mutagens or reprotoxic substances;

(c) the number of employees exposed;

(d) the preventive measures taken;

(e) the type of protective equipment used;

(f) the nature and degree of exposure; and

(g) the cases of replacement substances or mixtures used to reduce such exposure.

Unforeseen Exposure

6. (1) In the event of any unforeseeable event or an accident at the workplace which is likely to result in an abnormal exposure of employees to carcinogens, mutagens or reprotoxic substances, the employer shall inform their employees and the Authority as quickly as possible.

(2) Until the situation referred to in paragraph (1) has been restored to normal and the cause of abnormal exposure has been eliminated—

(a) only those employees who are essential to the carrying out of repairs and other necessary work shall be permitted to work in an area of abnormal exposure,

(b) employees so employed shall be provided with protective clothing and individual respiratory protection equipment,

(c) such exposure of employees shall not be permanent and shall be kept to the minimum time necessary for each employee, and

(d) unprotected employees shall not be allowed to work in an area of abnormal exposure.

(3) Taking account of the provisions of section 21 of the Act of 2005, the employer shall ensure that the provisions of paragraphs (1) and (2) are applied in relation to the employees of such other persons and self-employed persons who may be associated with such abnormal exposure to carcinogens, mutagens or reprotoxic substances.

(4) Every employee shall wear personal protective equipment provided by an employer in compliance with subparagraph (2)(b) and taking account of section 8 of the Act of 2005.

Foreseeable Exposure

7. (1) The employer, in respect of any activity where there is a potential for a significant increase in exposure of employees to carcinogens, mutagens or reprotoxic substances at the workplace, such as maintenance, and in respect of which all scope for further technical preventive measures for limiting employees' exposure has already been exhausted, shall—

(a) consult with the employees or their representatives on measures for limiting exposure by reducing the duration of exposure,

(b) provide employees with individual respiratory equipment and protective clothing during any period of abnormal exposure,

(c) ensure that exposure is not permanent and is kept to a minimum for each employee, and

(d) take appropriate measures to ensure that the areas in which abnormal exposure prevails are clearly demarcated and indicated or that unauthorised persons are prevented by other means from having access to such areas.

(2) Taking account of the provisions of section 21 of the Act of 2005, the employer shall ensure that the provisions of paragraph (1) are applied in relation to the employees of such other persons and self-employed persons where there is a potential for a significant increase in exposure to carcinogens, mutagens or reprotoxic substances.

(3) Every employee shall wear personal protective equipment provided by an employer in compliance with subparagraph (1)(b) and taking account of section 8 of the Act of 2005.

General measures

8. (1) In the case of any activity in relation to which there is a risk of contamination by carcinogens, mutagens or reprotoxic substances, the employer shall take appropriate measures to ensure that—

(a) employees do not eat or drink, or inhale nicotine or tobacco products, in any working area where there is such a risk,

(b) employees are provided with appropriate protective or other appropriate special clothing,

(c) separate storage places are provided for working or protective clothing and for ordinary clothes,

(d) personal protective equipment is properly stored in a designated place, and cleaned where possible and checked before use and in any case after each use, and

(e) such equipment found to be defective is reported, and repaired or replaced, as may be appropriate.

(2) Every employee shall comply with those measures set out in paragraph (1).

Information and Training of Employees

9. (1) The employer shall take appropriate measures to ensure that employees receive appropriate training and information concerning—

(a) potential risks to health, including any synergistic effects from other exposures,

(b) precautions to be taken to prevent exposure,

(c) hygiene requirements,

(d) the wearing and use of protective equipment and clothing,

(e) steps to be taken by employees including those to be taken during rescue operations, in the case of incidents and to prevent incidents,

(f) the consequences for employees' health or safety of the selection, wearing and use of protective clothing and equipment, and

(g) installations and related containers containing carcinogens, mutagens or reprotoxic substances and the significance of the labelling, warning and hazard signs.

(2) The training involved in paragraph (1) shall be—

(a) adapted to take account of new or changed risk, in particular when workers are or are 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,

(b) 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

(c) repeated periodically in other settings.

(3) Every employer shall ensure that either or both employees and their safety representatives—

(a) can check the means by which these Regulations are applied,

(b) can be involved in the implementation of these Regulations,

(c) are informed of the measures determined for limiting employee exposure referred to in Regulation 7, and

(d) are informed as quickly as possible of the type of exposure referred to in Regulation 6(1), of the causes thereof and of the measures taken or to be taken in relation thereto.

(4) Every employer shall—

(a) keep an up-to-date list of the employees engaged in the activities in respect of which the results of the assessment required by Regulation 4(2) reveal a risk to employees' health and safety, indicating, if the information is available, the exposure to which they have been subjected and this list shall be made available on request to the Authority, the doctor or other persons responsible for health and safety at work,

(b) ensure that each employee has access to the information on the list which relates to them personally, and

(c) ensure that either or both the employees and their safety representatives in the undertaking have access to anonymous collective information.

(5) Without prejudice to the provisions of this Regulation, the provisions of section 10 of the Act of 2005, apply to the requirements of these Regulations.

Consultation

10. The employer shall ensure that consultation of either or both employees and their safety representatives as regards the requirements of these Regulations, takes place in accordance with the provisions of section 9(3) of the Act of 2005.

Health Surveillance

11. (1) The employer shall ensure, unless otherwise stated in the Code of Practice, that relevant health surveillance is made available to every employee for whom the results of an assessment carried out under Regulation 4(2) reveal a risk to their health or safety—

(a) prior to exposure, and

(b) at regular intervals thereafter,

such that it is directly possible to implement individual and occupational hygiene measures.

(2) The employer shall ensure that—

(a) where an employee 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, health surveillance is made available to other employees, who may have been similarly exposed, whenever requested by the responsible medical practitioner or the Authority,

(b) where the surveillance required by subparagraph (a) is undertaken, a further re-assessment of the risk of exposure is made in accordance with Regulation 4(2),

(c) where an employee receives health surveillance under this Regulation, that an individual health record is kept of such matters,

(d) employees are provided with information and advice regarding any health surveillance they may undergo, and

(e) any employee may request a review of the results of any health surveillance they may undergo.

(3) The responsible medical practitioner, under whose responsibility an employee receives health surveillance, which may include biological monitoring and related requirements, under this Regulation, shall—

(a) keep an individual confidential medical record, and

(b) propose any protective or preventive measures necessary in respect of any individual employee.

(4) It shall be the duty of the responsible medical practitioner in respect of paragraph (3)(a) and the employer in respect of paragraph (2)(c) to provide access to the results of an employee's own health surveillance.

(5) It shall be the duty of the responsible medical practitioner to allow access to individual confidential medical records to an occupational medical adviser who is designated under section 63 of the Act of 2005.

(6) It shall be the duty of the responsible medical practitioner when carrying out relevant health surveillance required by this Regulation to take account of the Code of Practice.

(7) Following health surveillance, the responsible medical practitioner may indicate that health surveillance must continue after the end of exposure for as long as it is considered necessary to safeguard the health of the employee concerned.

(8) It shall be the duty of the employer or of any registered medical practitioner, including a responsible medical practitioner, to notify the Authority of any case of:

(a) cancer;

(b) adverse effects on sexual function and fertility in adult male or female employees; or

(c) developmental toxicity in the offspring of employees.

Exposure Record

12. (1) With regard to carcinogens and mutagens, the list referred to in Regulation 9(4)(a), the health record referred to in Regulation 11(2)(c) and the medical record referred to in Regulation 11(3)(a) shall be kept for at least 40 years following the end of the relevant exposure, and shall be deposited with the Authority if an employer ceases to be an employer for the purposes of these Regulations.

(2) With regard to reprotoxic substances, the list referred to in Regulation 9(4)(a), the health record referred to in Regulation 11(2)(c) and the medical record referred to in Regulation 11(3)(a) shall be kept for at least five years following the end of the relevant exposure, and shall be deposited with the Authority if an employer ceases to be an employer for the purposes of these Regulations.

Revocation

13. (1) The following are revoked:

(a) the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 (S.I. No. 78 of 2001);

(b) the Safety, Health and Welfare at Work (Carcinogens) (Amendment) Regulations 2015 (S.I. No. 622 of 2015); and

(c) the Safety, Health and Welfare at Work (Carcinogens) (Amendment) Regulations 2019 (S.I. No. 592 of 2019).

(2) References in other enactments to Regulations revoked under paragraph (1) shall, where the context so admits, be construed as references to these Regulations.

GIVEN under my hand,
27 March 2024

NEALE RICHMOND,
Minister of State at the Department of Enterprise, Trade and Employment.

EXPLANATORY NOTE

(*This note is not part of the instrument and does not purport to be a legal interpretation*.)

These Regulations give effect to 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.

Directive 2022/431 amends Directive 2004/37/EC by introducing reprotoxic substances as a group of chemicals to be regulated. Reprotoxic substances are chemicals which affect fertility, sexual function or have adverse effects on the offspring of workers. Reprotoxins were previously regulated under Directive 98/24/EC (the Chemical Agents Directive), but it was determined that it was more appropriate to regulate them under the stricter requirements of Directive 2004/37/EC.

These Regulations also introduce allowances for biological monitoring for those companies who wish to carry it out.

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