No. 813

OCCUPATIONAL HEALTH AND SAFETY AUTHORITY

Explanatory Notes[1]

Protection of Workers from the Risks related to Exposure to Carcinogens, Mutagens or Reprotoxic Substances at Work (Amendment) Regulations, 2026 & Protection of the Health and Safety of Workers from the Risks related to Chemical Agents at Work (Amendment) Regulations, 2026 (hereinafter referred to as "the amending regulations").

1. Introduction

Amendments to the Protection of Workers from the Risks related to Exposure to Carcinogens, Mutagens or Reprotoxic Substances at Work (S.L. 646.14) and the Protection of the Health and Safety of Workers from the Risks related to Chemical Agents at Work (S.L. 646.16) were carried out to transpose Directive (EU) 2024/869 of the European Parliament and of the Council of 13 March 2024 amending Directive 2004/37/EC of the European Parliament and of the Council and Council Directive 98/24/EC as regards the limit values for lead and its inorganic compounds and for diisocyanates (hereinafter referred to as the "Directive")

2. Summary and background

(i) Protection of Workers from the Risks related to Exposure to Carcinogens, Mutagens or Reprotoxic Substances at Work (Amendment) Regulations, 2026

The amending regulations introduce stricter limits on exposure to lead and establish harmonised methods for monitoring blood lead levels. These limits will be progressively strengthened over time, with the aim of enabling earlier detection and timely intervention to prevent chronic health conditions in workers.

The amending regulations also aim to strengthen the protection of workers by introducing stricter occupational exposure limits for lead and its inorganic compounds, and for diisocyanates.

Lead and its inorganic compounds are key occupational reprotoxic substances that can cause adverse effects on both fertility and the development of the foetus, while diisocyanates are skin and respiratory sensitisers that can have harmful respiratory health effects such as occupational asthma, bronchial hyper-responsiveness and isocyanate sensitisation, as well as dermal occupational disease.

(ii) Protection of the Health and Safety of Workers from the Risks related to Chemical Agents at Work (Amendment) Regulations, 2026

The amending regulations introduce revised Occupational Exposure Limit Values (OELVs) for lead and its inorganic compounds, setting a new binding limit of 0.03 mg/m³ (inhalable fraction) as an 8-hour time-weighted average (TWA), and classifying lead as a non-threshold reprotoxic substance.

Furthermore, the amending regulations aim at strengthening the protection of workers by introducing more stringent binding occupational exposure limits (OELs) for lead and its inorganic compounds and for diisocyanates, both of which are classified as hazardous substances with significant health risks, particularly affecting the nervous system and respiratory system, and posing reprotoxic and sensitisation hazards.

[1]These Explanatory Notes are in accordance with and for the purpose of article 3(2)(c) and Schedule III of the Small Business Act (Chapter 512 of the Laws of Malta).

Standardised exposure limits for diisocyanates, measured via NCO groups, helps to address both dermal and respiratory sensitisation, which are known to cause occupational asthma and other allergic reactions.

2.2 Public Consultation

The amending regulations were discussed with social partners represented on the OHSA's Governing Board, namely the Malta Chamber of SMEs (formerly the GRTU), the Malta Employees Association (MEA), and Representatives of Unions (the General Workers Union and the UĦM Voice of the Workers). There was a unanimous agreement to these amendments.

3. Overview of the structure of the instruments

(i) Protection of Workers from the Risks related to Exposure to Carcinogens, Mutagens or Reprotoxic Substances at Work (Amendment) Regulations, 2026

The amending regulations consist of five (5) regulations and as follows:

Regulation 1: Citation.

Regulation 2: Amends regulation 1 of the principal regulations.

Regulation 3: Amends regulation 2 of the principal regulations.

Regulation 4: Amends Schedule III to the principal regulations.

Regulation 5: Substitutes Schedule IV to the principal regulations.

(ii) Protection of the Health and Safety of Workers from the Risks related to Chemical Agents at Work (Amendment) Regulations, 2026

The amending regulations consist of four (4) regulations as follows:

Regulation 1: Citation.

Regulation 2: Amends regulation 1 of the principal regulations.

Regulation 3: Substitutes Schedule I to the principal regulations.

Regulation 4: deletes Schedule II to the principal regulations.

4. Commentary

(i) Protection of Workers from the Risks related to Exposure to Carcinogens, Mutagens or Reprotoxic Substances at Work (Amendment) Regulations, 2026

Regulation 3: Amends regulation 2 of the principal regulations to update the definition of "mutagen".

Regulation 4: Schedule III is being amended to introduce updated limit values for lead and its inorganic compounds, setting a binding occupational exposure limit of 0.03 mg/m³ (inhalable fraction), eight hours (TWA) and classifying it as a non-threshold reprotoxic substance.

Regulation 5: Substitutes Schedule IV to the principal regulations. The new Schedule introduces a staged reduction in the biological limit value for blood lead levels:

Until 31 December 2028: 30 µg Pb/100 ml blood;

From 1 January 2029: 15 µg Pb/100 ml blood

Additional requirements are being introduced for medical surveillance thresholds and special provisions for female workers of childbearing age.

(ii) Protection of the Health and Safety of Workers from the Risks related to Chemical Agents at Work (Amendment) Regulations, 2026

Regulation 3: Substitutes Schedule I to the principal regulations, whereby an occupational exposure limit of 6 µg NCO/m³ and a short-term exposure limit of 12 µg NCO/m³ are established for all diisocyanates, NCO refers to the isocyanate functional groups of diisocyanate compounds, and a skin, dermal and respiratory sensitisation notation is assigned. An occupational exposure limit of 10 µg NCO/m³, accompanied by an associated short-term exposure limit of 20 µg NCO/m³, shall apply for a transitional period until 31 December 2028.

Regulation 4: Deletes Schedule II which provided outdated limits.

5. Concluding Sections

The amending regulations shall come into force upon their publication in the Government Gazette and will be available on OHSA's website: https://www.ohsa.mt/

N.B: These Explanatory Notes are not intended to be an exhaustive description of the legal instrument nor a substitute thereof or a legislative supplement to it. These Explanatory Notes do not purport to be an authoritative ruling on the interpretation of the legislation.

Annex
Transposition Notes

Article/Provision of Directive (EU) No 2024/869	**Provision in S.L. 646.14**
Article 1 Article 2 Annex II Annex IIIa	Regulation 1 Regulation 2 Regulation 3 Regulation 4 Regulation 5

Article/Provision of Directive (EU) No 2024/869	**Provision in S.L. 646.16**
Article 1 Article 2 Annex I	Regulation 1 Regulation 2 Regulation 3 Regulation 4

26th May, 2026