No. 442

MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY

Explanatory Notes

1. Introduction

Title of Regulations	Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2024 (hereinafter referred to as the "amending regulations")
Activity to be regulated	The restriction of the use of certain hazardous substances in electrical and electronic equipment
Responsible entity	The Technical Regulations Division (TRD) within the Malta Competition and Consumer Affairs Authority (MCCAA)

2. Summary and background

2.1 Aims & Objectives of the legislation

Directive 2011/65/EU lays down rules on the restriction of the use of hazardous substances (RoHS) in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of EEE waste.

Directive 2011/65/EU applies to eleven different categories of EEE, listed in Annex I to that Directive.

Member States shall ensure that EEE placed on the market shall not exceed the maximum concentration values on the restricted substances as listed in Annex II of that Directive. However, while certain equipment is excluded from the scope of the Directive, as indicated in Article 2 thereof, a number of exemptions are granted, as listed in Annex III and Annex IV of the same Directive.

Information on **Directive 2011/65/EU of the European Parliament and of the Council** on the restriction of the use of hazardous substances in electrical and electronic equipment may be accessed through the following link:
http://ec.europa.eu/environment/waste/rohs_eee/index_en.htm

Directive 2011/65/EU and subsequent amendments thereto, have been transposed into local legislation by means of the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment Regulations (S.L. 427.57) (hereinafter referred to as the "principal regulations), which may be accessed through the following link:
https://legislation.mt/eli/sl/427.57/eng/pdf

The aim of the amending regulations is to transpose into Maltese law further amendments carried out to Directive 2011/65/EU. The amendments are included in Commission Delegated Directives (EU) 2023/1437 and 2023/1526, as indicated in regulation 1(2) of the amending regulations.

2.2 Overview of the Directives being transposed

Commission Delegated Directive (EU) 2023/1437:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023L1437
provides an exemption for mercury in melt pressure transducers for capillary rheometers under certain conditions.

Commission Delegated Directive (EU) 2023/1526:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023L1526
provides an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in vitro diagnostic medical devices.

3. Overview of the structure of the instrument

The amending regulations consist of three regulations.

4. Commentary on parts and articles of the legislation

Regulation No. of draft L.N.	Meaning & obligations placed on user
1	The title, the scope, and the date of entry into force of the amending regulations.
2(a)	Directive (EU) 2023/1526 provides an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in vitro diagnostic medical devices. Item 41a is being added to the list of the exemptions listed in Schedule IV to principal regulations for the purpose of adaptation to scientific and technical progress. This provision shall apply from 1st February 2024.
2(b)	Directive (EU) 2023/1437 provides an exemption for mercury in melt pressure transducers for capillary rheometers under certain conditions. Item 49 is being added to the list of the exemptions listed in Schedule IV to S.L. 427.57 for the purpose of adaptation to scientific and technical progress. This provision shall apply from 1st February 2024.
3	The Directives which are being transposed by means of the proposed regulations are listed in Schedule VIII to the principal regulations.

5. Concluding Section

These regulations shall be deemed to have come into force on 1st February 2024.

Should more information be required kindly contact the Regulatory Affairs Directorate within the Malta Competition and Consumer Affairs Authority on 23952000.

N.B. These Explanatory Notes are not intended to be an exhaustive description of the 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

(for the purpose of paragraph (vi) of Schedule III of Chapter 512 of the Laws of Malta)

Transposition Notes for the implementation of the main elements of the Directives mentioned in section 2.2 of this Explanatory Note.

Directive and Article number	Implementing regulation	Applicability date
Article 1 of Directive (EU) 2023/1437	Regulation 2(b)	1st February 2024
Article 1 of Directive (EU) 2023/1526	Regulation 2(a)	1st February 2024

28th March, 2024