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MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY
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Our Ref. RoHS 2023/01

Your Ref.

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User Guidelines

1. Introduction

Title of Regulations	Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2023
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. Objectives & Purpose 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 waste EEE.

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 the **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 **Subsidiary Legislation 427.57** (S.L. 427.57), entitled the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment Regulations, which may be accessed through the following link:

https://legislation.mt/eli/sl/427.57/eng/pdf

The objective of the proposed regulations is to transpose into Maltese law further amendments carried out to Directive 2011/65/EU. The amendments are included in two Commission Delegated Directives, as indicated in regulation 1(2) of the proposed regulations.

The Directives which are being transposed may be accessed through the following links:

Commission Delegated Directive (EU) 2022/1631:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L1631

Commission Delegated Directive (EU) 2022/1632:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022L1632

The Directives whose provisions are being transposed by means of the draft Legal Notice are:

Commission Delegated Directive (EU) 2022/1631 of 12 May 2022 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections.

Objective of this Directive:

- Directive 2011/65/EU lists Lead as a restricted substance in Annex II.
- In March 2019, the Commission received an application for an exemption to be listed in Annex IV to the RoHS Directive, for the use of lead in bismuth strontium calcium copper oxide (BSCCO) superconductor for use in cables and wires and lead in related electrical connections to other EEE components.
- The evaluation of the requested exemption included a technical and scientific assessment study, whereby it was concluded that the addition of lead to BSCCO provides technical and functional advantages which cannot be achieved without the use of lead. Those technical and functional advantages consist in higher resolution images for medical diagnosis or for research and innovation and allow a more stable operation mode of the relevant applications.
- Therefore, it is currently not possible to substitute or otherwise eliminate lead in superconducting material and related solders with the same technical performance, nor is it expected to be so in the foreseeable future. Therefore, the requested exemption is being granted, for an extensive validity period of five years, which expires on the 30th of June 2027.

Commission Delegated Directive (EU) 2022/1632 of 12 May 2022 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in certain magnetic resonance imaging devices.

Objective of this Directive:

- Directive 2011/65/EU lists Lead as a restricted substance in Annex II.
- The Commission has granted an exemption for the use of lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors that are used in certain medical magnetic resonance imaging (MRI) equipment, by Commission Delegated Directive 2014/7/EU, which exemption had to expire on the 30th of June 2020.
- The evaluation of the renewal application, received by the Commission, included a technical and scientific assessment study, whereby it was concluded that old design MRI devices depend on lead-containing MRI components and are highly limited in their compatibility with new lead-free MRI components. Also, a distinction should be made between MRIs with integrated coils and MRIs with non-integrated coils.

- Thus, in view of the above, as regards newly designed MRI devices with lead-containing integrated coils, additional time is required for the technical development of lead-free solutions, thus requiring a renewal of exemption for the use of lead. On the other hand, the use of lead in newly designed non-integrated MRI coils and in upcoming lead-free MRI devices with integrated coils should be excluded and revoked from the exemption.

- However, the renewed exemptions apply only for a specific period and therefore MRI devices cannot be placed on the market after the dates specified in the exemption if they contain lead.

- Therefore, by not granting the renewal request may result in premature wastage of MRI devices due to a lack of compatible components or redesigning options. This could result in a supply gap of MRI equipment, which could in turn adversely affect health care for patients.

- The total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof. Therefore, in order to provide compatible MRI equipment for health services and to allow time for the development of lead-free alternatives, the renewal of the exemption is being granted, with a revised scope, for the maximum duration of 7 years until the 30th of June 2027.

Both exemptions are consistent with REACH Regulation and thus do not prejudice the environmental and health protection afforded by them, while the duration of the exemption is unlikely to have adverse impacts on innovation, owing to the results of the ongoing efforts to find a reliable substitution.

Provisions in Directives (EU) 2022/1631 and 2022/1632 shall apply from 1st March 2023.

3. Commentary on parts and articles

Regulation No. of draft L.N.	Meaning & obligations placed on user
1	The title, the scope, and the date for coming into force of the proposed regulations of the draft Legal Notice.
2(a)	Directive (EU) 2022/1632 provides an exemption for the use of lead in certain magnetic resonance imaging devices. Item 27 of the exemptions listed in Schedule IV to S.L. 427.57 is being substituted for the purpose of adaptation to scientific and technical progress. This provision shall apply from 1st March 2023.
2(b)	Directive (EU) 2022/1631 provides an exemption for the use of lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections.

	Item 48 of the exemptions listed in Schedule IV to S.L. 427.57 is being added for the purpose of adaptation to scientific and technical progress. This provision shall apply from 1st March 2023.
3	The two Directives which are being transposed by the proposed regulations are listed in Schedule VIII to S.L. 427.57.

***Disclaimer**: The information contained within this document is intended only as guidelines and is not intended, nor should be construed, as legislation. Please refer to the related legal notice for a more comprehensive understanding.*

For any other information kindly contact the Regulatory Affairs Directorate within the Technical Regulations Division of the Malta Competition and Consumer Affairs Authority using the following contact details:

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