

Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 20,011, 19 ta' Ġunju, 2018

Taqsimha B

L.N. 196 of 2018

**PRODUCT SAFETY ACT
(CAP. 427)**

**Restriction of Use of Hazardous Substances in Electrical and
Electronic Equipment (Amendment) Regulations, 2018**

IN exercise of the powers conferred by articles 38 and 39 of the Product Safety Act, the Minister for Ministry for Justice, Culture and Local Government, on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:-

1. (1) The title of these regulations is the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2018, and these regulations shall be read and construed as one with the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment Regulations, hereinafter referred to as "the principal regulations".

Citation and coming into force.

S.L. 427.57

(2) Regulation 4(a), (b), (c) shall apply as from 6th July 2018 and regulation 4(d) shall apply as from 21st November 2018.

2. Sub-regulation (IA), including paragraphs (a) to (f) of regulation 2 of the principal regulations shall be deleted.

Amends regulation 2 of the principal regulations.

3. Regulation 2A of the principal regulations shall be substituted by the following:

Substitutes regulation 2A of the principal regulations.

"2A. These regulations implement the following European Union legislation:

(a) the requirements of Article 14(2)(e), Article 14(4), Article 15(2) and Annex IX of Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast);

(b) Commission Delegated Directive 2014/1/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation;

(c) Commission Delegated Directive 2014/2/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in phosphor coatings in image intensifiers for X-ray images until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020;

(d) Commission Delegated Directive 2014/3/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead acetate marker for use in stereotactic head frames for use with CT (Computed Tomography) and MRI and in positioning systems for gamma beam and particle therapy equipment;

(e) Commission Delegated Directive 2014/4/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers;

(f) Commission Delegated Directive 2014/5/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards, termination coatings of electrical and electronic components and coatings of printed circuit boards, solders for connecting wires and cables, solders connecting transducers and sensors that are used durably at a temperature below -20°C under normal operating and storage conditions;

(g) Commission Delegated Directive 2014/6/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in the surface coatings of pin connector systems requiring non-magnetic connectors which are used durably at a temperature below -20°C under normal operating and storage conditions;

(h) Commission Delegated Directive 2014/7/EU of

18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders, termination coatings of electrical and electronic components and printed circuit boards, connections of electrical wires, shields and enclosed connectors which are used (a) in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, including patient monitors designed to be used within this sphere, or (b) in magnetic fields within 1 m distance from the external surfaces of cyclotron magnets, magnets for beam transport and beam direction control applied for particle therapy;

(i) Commission Delegated Directive 2014/8/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders for mounting cadmium telluride and cadmium zinc telluride digitalarray detectors to printed circuit boards;

(j) Commission Delegated Directive 2014/9/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors;

(k) Commission Delegated Directive 2014/10/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in alloys, as a superconductor or thermal conductor, used in cryo-cooler cold heads and/or in cryo-cooled cold probes and/or in cryo-cooled equipotential bonding systems, in medical devices (category 8) and/or in industrial monitoring and control instruments;

(l) Commission Delegated Directive 2014/11/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as

regards an exemption for hexavalent chromium in alkali dispensers used to create photocathodes in X-ray image intensifiers until 31 December 2019 and in spare parts for X-ray systems placed on the EU market before 1 January 2020;

(m) Commission Delegated Directive 2014/12/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on printed circuit boards of detectors and data acquisition units for Positron Emission Tomographs which are integrated into Magnetic Resonance Imaging equipment;

(n) Commission Delegated Directive 2014/13/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators;

(o) Commission Delegated Directive 2014/14/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for 3,5 mg mercury per lamp in single capped compact fluorescent lamps for general lighting purposes < 30 W with a lifetime equal to or above 20 000 h;

(p) Commission Delegated Directive 2014/15/EU of 18 October 2013 amending, for the purposes of adapting to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer;

(q) Commission Delegated Directive 2014/16/EU of 18 October 2013 amending, for the purposes of adapting

to technical progress, the Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi 2O5:Pb) phosphors;

(r) Commission Delegated Directive 2014/69/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in dielectric ceramic in capacitors for a rated voltage of less than 125 V AC or 250 V DC for industrial monitoring and control instruments;

(s) Commission Delegated Directive 2014/70/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in micro-channel plates (MCPs);

(t) Commission Delegated Directive 2014/71/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solder in one interface of large area stacked die elements;

(u) Commission Delegated Directive 2014/72/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems;

(v) Commission Delegated Directive 2014/73/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinised platinum electrodes used for conductivity measurements;

(w) Commission Delegated Directive 2014/74/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of

the European Parliament and of the Council as regards an exemption for lead used in other than C-press compliant pin connector systems for industrial monitoring and control instruments;

(x) Commission Delegated Directive 2014/75/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in cold cathode fluorescent lamps (CCFLs) for back-lighting liquid crystal displays, not exceeding 5 mg per lamp, used in industrial monitoring and control instruments placed on the market before 22 July 2017;

(y) Commission Delegated Directive 2014/76/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for Mercury in hand crafted luminous discharge tubes (HLDTs) used for signs, decorative or architectural and specialist lighting and light-artwork;

(z) Commission Delegated Directive (EU) 2015/573 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/ EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices;

(aa) Commission Delegated Directive (EU) 2015/574 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/ EU of the European Parliament and of the Council as regards an exemption for mercury in intravascular ultrasound imaging systems;

(bb) Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/ EU of the European Parliament and of the Council as regards the list of restricted substances;

(cc) Commission Delegated Directive (EU) 2016/585 of 12 Feb 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive

2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes;

(dd) Commission Delegated Directive (EU) 2016/1028 of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders of electrical connections to temperature measurement sensors in certain devices; and

(ee) Commission Delegated Directive (EU) 2016/1029 of 19 April 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium anodes in Hersch cells for certain oxygen sensors used in industrial monitoring and control instruments;

(ff) Commission Delegated Directive (EU) 2017/1009 of 13 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium and lead in filter glasses and glasses used for reflectance standards;

(gg) Commission Delegated Directive (EU) 2017/1010 of 13 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in bearing shells and bushes for certain refrigerant-containing compressors;

(hh) Commission Delegated Directive (EU) 2017/1011 of 15 March 2017 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in white glasses used for optical applications; and

(ii) Commission Delegated Directive (EU) 2017/

1975 of 7 August 2017 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for cadmium in colour converting light-emitting diodes (LEDs) for use in display systems."

Amends
Schedule III to
the principal
regulations.

4. Schedule III to the principal regulations shall be amended as follows:

(a) item 13(b) thereof shall be substituted by the following:

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| "13(b) Cadmium and lead in filter glasses and glasses used for reflectance standards | Applies to categories 8, 9 and 11; expires on: |
| | — 21 July 2023 for category 8 in vitro diagnostic medical devices; |
| | — 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11; |
| | — 21 July 2021 for other subcategories of categories 8 and 9 |
| 13(b)-(I) Lead in ion coloured optical filter glass types | Applies to categories 1 to 7 and 10; expires on 21 July 2021 for categories 1 to 7 and 10 |
| 13(b)-(II) Cadmium in striking optical filter glass types; excluding applications falling under point 39 of this Annex | |
| 13(b)-(III) Cadmium and lead in glazes used for reflectance standards | "; |

(b) item 9(b) thereof shall be substituted by the following:

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| "9(b) Lead in bearing shells and bushes for refrigerant-containing compressors for heating, ventilation, air conditioning and refrigeration (HVACR) applications | Applies to categories 8, 9 and 11; expires on: |
| | — 21 July 2023 for category 8 in vitro diagnostic medical devices, |
| | — 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11, |
| | — 21 July 2021 for other subcategories of categories 8 and 9. |

9(b)-(I) Lead in bearing shells and bushes for refrigerant-containing hermetic scroll compressors with a stated electrical power input equal or below 9 kW for heating, ventilation, air conditioning and refrigeration (HVACR) applications

Applies to category 1; expires on 21 July 2019.

”;

(c) item 13(a) thereof shall be substituted by the following:

”13(a) Lead in white glasses used for optical applications

Applies to all categories; expires on:

- 21 July 2023 for category 8 in vitro diagnostic medical devices;
- 21 July 2024 for category 9 industrial monitoring and control instruments and for category 11;
- 21 July 2021 for all other categories and subcategories”;

and

(d) item 39 thereof shall be substituted by the following:

”39(a) Cadmium selenide in downshifting cadmium-based semiconductor nanocrystal quantum dots for use in display lighting applications (< 0,2 µg Cd per mm² of display screen area)

Expires for all categories on 31 October 2019.

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