Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 19,233, 8 ta' April, 2014
Taqsima B

L.N. 118 of 2014

PRODUCT SAFETY ACT (CAP. 427)

Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2014

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, Minister for Social Dialogue, Consumer Affairs and Civil Liberties, on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2014, 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".

S.L.427.57

Implementation.

2. 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 digital array 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 2 O 5 :Pb) phosphors.

Amends regulation 3 of the principal regulations.

3. Regulation 3 of the principal regulations shall be amended as follows:

(a) for the definition "Technical Regulations Division", there shall be substituted the following:

" "Technical Regulations Division" means the Technical Regulations Division established by article 19 of the Malta Competition and Consumer Affairs Authority Act, hereinafter referred to as "competent authority";"; and

(b) immediately after the new definition "Technical Regulations Division", there shall be added the following new definition:

" "waste electrical and electronic equipment" or "WEEE" means electrical and electronic equipment which is waste as defined in regulation 4 of the Waste Regulations, including all components, sub-assemblies and consumables which are part of the product at the time of discarding;".

Adds new regulation to the principal regulations.

4. Immediately after regulation 4 of the principal regulations, there shall be added the following new regulation:

"Competent authority.

4A. (1) The competent authority shall ensure that users of EEE in private households are given the necessary information about the meaning of the symbol shown in Schedule VII.

(2) In order to enable the date upon which the EEE was placed on the market to be determined unequivocally, the competent authority shall ensure that a mark on the EEE specifies that the latter was placed on the market after 13 August 2005. Preferably, the European Standard EN 50419 shall be applied for this purpose.

(3) With a view to minimising the disposal of WEEE as unsorted municipal waste and to facilitating its separate collection, the competent authority shall ensure that producers appropriately mark - preferably in accordance with the European standard EN 50419 - EEE placed on the market with the symbol shown in Schedule VII. In exceptional cases, where this is necessary because of the size or the function of the product, the symbol shall be printed on the packaging, on the instructions for use and on the warranty of the EEE.".

Amendment of Schedule III of the principal regulations.

5. Immediately after item 1(f) in Schedule III of the principal regulations, there shall be added the following new item:

"

1(g)	For general lighting purposes < 30 W with a lifetime equal or above 20 000 h: 3,5 mg	Expires on 31 December 2017

Amendment of Schedule IV of the principal regulations.

6. Schedule IV of the principal regulations shall be amended as follows:

(a) item 12 thereof shall be substituted by the following:

"12. Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors. Expires on 30 June 2021."; and

(b) immediately after item 20 thereof, there shall be added the following new items:

"21. 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.

22. Lead acetate marker for use in stereotactic head frames for use with CT and MRI and in positioning systems for gamma beam and particle therapy equipment. Expires on 30 June 2021.

23. Lead as an alloying element for bearings and wear surfaces in medical equipment exposed to ionising radiation. Expires on 30 June 2021.

24. Lead enabling vacuum tight connections between aluminium and steel in X-ray image intensifiers. Expires on 31 December 2019.

25. Lead in the surface coatings of pin connector systems requiring nonmagnetic connectors which are used durably at a temperature below -20°C under normal operating and storage conditions. Expires on 30 June 2021.

26. 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. Expires on 30 June 2021.

27. 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 in

(a) 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) 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. Expires on 30 June 2020.

28. Lead in solders for mounting cadmium telluride and cadmium zinc telluride digital array detectors to printed circuit boards. Expires on 31 December 2017.

29. 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. Expires on 30 June 2021.

30. 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.

31. 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. Expires on 21 July 2021.

32. 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. Expires on 31 December 2019.

33. 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. Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb.'

34. Lead as an activator in the fluorescent powder of discharge lamps when used for extracorporeal photopheresis lamps containing BSP (BaSi 2 O 5 :Pb) phosphors. Expires on 22 July 2021.".

Adds new schedule to the principal regulations.

7. Immediately after Schedule VI to the principal regulations, there shall be added the following new schedule:

"Schedule VII

The symbol indicating separate collection for EEE consists of the crossed-out wheeled bin, as shown below. The symbol must be printed visibly, legibly and indelibly.

".

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — *Printed at the Government Printing Press on recycled paper*

Prezz/*Price*
€0.36