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MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY
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Our Ref. RoHS 2022/01

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User Guidelines

1. Introduction

Title of Regulations	Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations, 2022
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 different categories of EEE, categories 1 to 11, which are 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, certain equipment is excluded from the scope of the Directive, as indicated in Article 2 thereof; while 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 can 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 **Subsidiary Legislation 427.57** (S.L. 427.57), Restriction of Use of Hazardous Substances in Electrical and Electronic Equipment Regulations, which can 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 contained in three Commission Delegated Directives, as indicated in regulation 1(2) of the proposed regulations.

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

Commission Delegated Directive (EU) 2021/1978:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L1978&qid=1641298951077

Commission Delegated Directive (EU) 2021/1979:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L1979&qid=1641298990047

Commission Delegated Directive (EU) 2021/1980:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L1980&qid=1641299026384

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

Commission Delegated Directive (EU) 2021/1978 of 11 August 2021 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 bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices.

Objective of this Directive:

- Directive 2011/65/EU lists bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) as restricted substances in Annex II, applicable from 21st July 2021.
- Currently, the restriction of DEHP, BBP, DBP and DIBP is not to apply to spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of medical devices, including *in vitro* medical devices, placed on the market *before* 22nd July 2021.
- Hence, a request was made for an exemption for the use of DEHP, BBP, DBP and DIBP in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, that are placed on the market *after* 21st July 2021.
- The request was evaluated and concluded that the total negative environmental and health impacts of substituting refurbished parts containing DEHP, BBP, DBP and DIBP with new substance-free refurbished parts are likely to outweigh the total environmental and health benefits.
- It is, therefore, appropriate to grant the requested exemption, in Annex IV to Directive 2011/65/EU. But, in order to ensure a high level of protection for the environment, health and consumer safety, reuse should take place in auditable closed-loop business-to-business return systems and reuse of spare parts should be notified to the customer.
- The requested exemption is granted for a duration of 7 years starting retroactively from 21st July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.
- The exemption is also consistent with the REACH Regulation.

Commission Delegated Directive (EU) 2021/1979 of 11 August 2021 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 bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils.

Objective of this Directive:

- Directive 2011/65/EU lists bis(2-ethylhexyl) phthalate (DEHP) as a restricted substance in Annex II, and it is not to be used, from 22nd July 2021, in medical devices, including *in vitro* medical devices, above a maximum concentration value of 0,1% tolerated by weight in homogeneous materials.

- The evaluation of the requests for an exemption for the use of DEHP in plastic components in MRI detector coils, which took into account the availability of technically practicable and reliable substitutes and the socioeconomic impact of substitution, concluded that no suitable alternatives to DEHP are sufficiently available on the market and that not granting the exemption is likely to result in total negative environmental, health and consumer safety impacts caused by substitution, which outweigh the benefits.

- It is, therefore, appropriate to grant the requested exemption, for the use of DEHP in plastic components in MRI detector coils, in Annex IV to Directive 2011/65/EU.

- The requested exemption is granted until 1st January 2024, starting retroactively from 21st July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

- The exemption is also consistent with the REACH Regulation.

Commission Delegated Directive (EU) 2021/1980 of 11 August 2021 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 bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids.

Objective of this Directive:

- Directive 2011/65/EU lists bis(2-ethylhexyl) phthalate (DEHP) as a restricted substance in Annex II, and it is not to be used, from 22nd July 2021, in medical devices, including *in vitro* medical devices, above a maximum concentration value of 0,1% tolerated by weight in homogeneous materials.

- DEHP is used as a membrane solvent of ion selective electrodes applied in point of care analysers which help to measure the concentration of ionic substances in human body fluids and/or in dialysate fluids.

- The evaluation of the request for an exemption for the use of DEHP in ion-selective electrodes for analysing human body fluids and/or dialysate fluids, concluded that alternatives to DEHP are currently not sufficiently reliable and that the substitution of DEHP in specific applications would result in negative environmental and health impacts that outweigh its benefits.

- It is, therefore, appropriate to grant the requested exemption, for the use of DEHP in ion-selective electrodes for analysing human body fluids and/or dialysate fluids, in Annex IV to Directive 2011/65/EU.

- The requested exemption is granted for a duration of 7 years starting retroactively from 21st July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

- The exemption is also consistent with the REACH Regulation.

Provisions from Directives (EU) 2021/1978, 2021/1979 and 2021/1980 shall apply retroactively from 21st July 2021.

3. Commentary on parts and articles

Regulation No. of draft L.N.	Meaning & obligations placed on user
1	The title, the three Directives that are being transposed, and the retroactive date for coming into force of the new regulations of the draft Legal Notice.
2	Directive (EU) 2021/1978 provides an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices. Directive (EU) 2021/1979 provides an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils. Directive (EU) 2021/1980 provides an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids. Items 45, 46 and 47 are being added to the exemptions listed in Schedule IV to S.L. 427.57, for the purpose of adaptation to scientific and technical progress. These three provisions shall apply retroactively from 21st July 2021.
3	The three Directives that are being transposed by the new 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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