

Commission Delegated Directive (EU) 2016/585 of 12 February 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 (Text with EEA relevance)

COMMISSION DELEGATED DIRECTIVE (EU) 2016/585

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment⁽¹⁾, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) Directive 2011/65/EU prohibits the use of lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in electrical and electronic equipment placed on the market.
- (2) Refurbishment practices exist for imaging equipment such as magnetic resonance imaging devices, computer tomography devices, *in vitro* diagnostic devices, patient monitoring devices, and electron microscopes. Some of the recovered spare parts reused for refurbishment will contain small amounts of lead, cadmium, hexavalent chromium, or PBDE.
- (3) The exemption set out in point 31 of Annex IV to Directive 2011/65/EU does not allow for the use of spare parts recovered from used equipment which was not already placed on the Union market thus limiting the availability of recovered spare parts.
- (4) A comparison of the environmental impacts of using refurbished parts in such cases with the environmental impacts of substituting refurbished parts with new ones demonstrates that the total negative environmental, health and consumer safety impacts of substitution would outweigh the total benefits thereof.

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- (5) Considering that the substance restriction will start to apply to the different equipment concerned on different dates as provided for in Article 4(3) of Directive 2011/65/EU, a different expiry date for the exemption should be set for each type of equipment.
- (6) Directive 2011/65/EU should therefore be amended accordingly.
- (7) In order to ensure a smooth transition for market operators from the existing provisions to those specified in this Directive and to prevent single market disruptions, it is appropriate to set a date for the simultaneous application by the Member States of their national provisions which also provides a reasonable period of time after the date of transposition,

HAS ADOPTED THIS DIRECTIVE:

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(1) [OJ L 174, 1.7.2011, p. 88.](#)