DIRECTIVES

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)

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 exists 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.

(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,

[1] OJ L 174, 1.7.2011, p. 88.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 28 February 2017, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 6 November 2017.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 12 February 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex IV to Directive 2011/65/EU is amended as follows:

(1) point 31 is deleted;

(2) the following point 31a is added:

'31a. Lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.

Expires on:

(a) 21 July 2021 for the use in medical devices other than *in vitro* diagnostic medical devices;

(b) 21 July 2023 for the use in *in vitro* diagnostic medical devices;

(c) 21 July 2024 for the use in electron microscopes and their accessories.'