

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 (Text with EEA relevance)

COMMISSION DELEGATED DIRECTIVE 2014/15/EU

of 18 October 2013

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(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<sup>(1)</sup>, and in particular Article 5(1)(a) thereof,

Whereas:

- (1) Directive 2011/65/EU prohibits the use of lead, cadmium and hexavalent chromium in electrical and electronic equipment placed on the market.
- (2) The most commonly re-used medical parts are X-ray tubes, MRI coils, printed circuit boards from many different types of equipment, and detectors and components of detectors (e.g. radiation detectors). Some of these will contain small amounts of lead, cadmium and hexavalent chromium.
- (3) Comparing the environmental impacts of using refurbished parts in the above mentioned cases to those 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.
- (4) Directive 2011/65/EU should therefore be amended accordingly,

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 bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by the last day of the sixth month after entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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, 18 October 2013.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX

In Annex IV to Directive 2011/65/EU the following point 31 is added:

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.

- (1) OJ L 174, 1.7.2011, p. 88.