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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	18 October 2013
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2013) 6838 final
Subject:	COMMISSION DELEGATED DIRECTIVE ../…/EU of 18.10.2013 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

Delegations will find attached document C(2013) 6838 final.

Encl.: C(2013) 6838 final

EUROPEAN
COMMISSION

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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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Subject: Commission Delegated Directive amending, for the purposes of adapting to technical progress, Annex IV of the Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for applications containing lead, cadmium and hexavalent chromium.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2) restricts the use of certain hazardous substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers) in electrical and electronic equipment. RoHS 2 (recast) entered into force on 21 July 2011.

RoHS 2 Annexes III and IV list exemptions of materials and components from the RoHS 2 substance restrictions. Article 5 provides for the adaptation (inclusion and deletion of exemptions) of the Annexes to scientific and technical progress. Pursuant to Article 5, exemptions shall be included in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 and where any of the following conditions is fulfilled: their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable; the reliability of substitutes is not ensured; or the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

RoHS 2 Article 5 establishes a procedure for the adaption of the Annexes to scientific and technical progress. RoHS 2 Article 5(1)(a) provides that the Commission shall include materials and components of EEE for specific applications in the lists in Annexes III and IV by means of individual delegated acts.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In line with the provisions for granting, renewing or revoking an exemption, which allow stakeholders to apply for an exemption from the substance restrictions (Article 5(3)), the Commission has received more than 30 requests for new exemptions since the publication of RoHS 2. With a view to the evaluation of the requested exemptions, the Commission commissioned a study and carried out the requisite technical and scientific assessment including an official stakeholder consultation.[1] The final study is available on the consultants' webpage; stakeholders and Member States were notified.[2] The project page is accessible via the DG Environment webpage.

[1] The consultation list is regularly updated and maintained by the consultants in cooperation with the Commission, and includes electronics related industry organisations, manufacturers and suppliers, recyclers, consumer associations, NGOs, academia, Member States' representatives etc.

[2] http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/20130412_RoHS2_Evaluation_Proj2_Pack1_Ex_Requests_1-11_Final.pdf.

Subsequently, the Commission consulted the official expert group for delegated acts under RoHS 2. A meeting with consultants and experts was held on 8 February 2013, and experts were invited to comment on the proposal by 24 March 2013. The expert group unanimously supported the proposal. All necessary steps pursuant to Article 5(3) to (7) have been performed. Council and Parliament were notified of all activities.

Article 4(4)(b) of the RoHS 2 Directive permits the use of spare parts containing Annex II substances, for the repair, the reuse, the updating of functionalities or the upgrading of capacities of medical devices that will be placed on the EU market before 22 July 2014. This article does therefore not apply to equipment placed on the market after this date.

With respect to the inclusion of 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", the evaluation results show that the relevant criteria specified in Article 5(1)(a) are fulfilled and the inclusion of the specific application in the exemptions listed in Annex IV is justified. The exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006. The total negative environmental and health impacts of alternatives outweigh the benefit of substitution. The major aspects are that:

– 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.

– Repairable assemblies in medical equipment generally have a good quality closed loop business to business system.

– In the above mentioned cases, the reuse of parts from used assemblies will have a smaller negative impact on the environment than if there was no re-use of parts.

– Not granting the exemption would result in negative impacts to the environment in terms of consumption of resources and in terms of greater quantities of waste that would outweigh the positive impacts of restricting the reuse of refurbished medical parts containing lead, cadmium and hexavalent chromium.

– Comparing the environmental impacts of using refurbished parts to that 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.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The proposed act grants an exemption from the substance restrictions in Annex II of Directive 2011/65/EU (RoHS 2), to be listed in Annex IV, for the use of lead, cadmium and hexavalent chromium in specific applications.

The proposed instrument is a delegated directive.

The draft delegated directive implements Directive 2011/65/EU, and in particular Article 5(1)(a) thereof.

The objective of the proposed act is to ensure legal certainty and sustainable market conditions for electronic manufacturers, by allowing specific applications of otherwise banned substances in line with the provisions of RoHS 2 and the therein established procedure for the adaption of the Annexes to scientific and technical progress.

In accordance with the principle of proportionality, the measure does not go beyond what is necessary to achieve its objective.

The proposal has no implications for the EU budget.

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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)

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,[3] 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,

[3] 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 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, 18.10.2013

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."