EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) XXX draft

COMMISSION DELEGATED DIRECTIVE (EU) .../…

of XXX

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Subject: Commission Delegated Decision 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, hexavalent chromium, and polybrominated diphenyl ethers (PBDE).

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2)[1] restricts the use of certain hazardous substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers) in electrical and electronic equipment. RoHS 2 (recast) entered into force on 21 July 2011.

The restricted substances are listed in Annex II of RoHS 2. Annexes III and IV of RoHS 2 list the materials and components of EEE for specific applications exempted from the substance restriction in RoHS 2 Article 4(1).

RoHS 2 Article 5 provides for the adaptation to scientific and technical progress (inclusion and deletion of exemptions) of Annexes III and IV. Pursuant to Article 5(1)a, 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.

Article 5 establishes a procedure for the adaptation of the Annexes to scientific and technical progress. Article 5(1) provides that the European Commission (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 in accordance with RoHS 2 Article 20.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In line with the provisions in Article 5(3) and Annex V for granting, renewing or revoking an exemption, which allows stakeholders to apply for an exemption of the restricted substance, the Commission has received almost 50 requests for new exemptions since the publication of RoHS 2 and almost 100 requests to renew existing exemptions.

The Commission received an application in June 2013 in relation to use of spare parts in medical devices in the context of RoHS; the use of spare parts as requested in the application is different than exemption 31 in Annex IV. With a view to evaluate the application, the Commission commissioned studies and carried out the requisite technical and scientific assessment including an official stakeholder consultation[2] for the application[3].

---

1 OJ L 174, 1.7.2011, p. 88.

2 http://ec.europa.eu/environment/consultations/rohs9_en.htm; consultation period from 20.12.2013 to 28.02.2014

3 The list of consulted stakeholders 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.

The final report for the evaluation of this application and a subsequent more comprehensive study on the broader issue of refurbishment of medical devices in the context of RoHS, both prepared by consultants Oeko Institute and approved by DG Environment, are available on the consultants' webpage[4]; stakeholders and Member States were notified. The project page is accessible via the DG Environment webpage[5].

Subsequently, the Commission consulted the official expert group for delegated acts under RoHS 2. A meeting with consultants and experts was held on 23 February 2015, a consolidated draft proposing a replacement of previous exemption 31 in order to allow a better use of spare parts recovered from used equipment which was not already placed on the EU market was sent out after the meeting and experts were invited to comment on the draft by 15 April 2015. The expert group broadly supported the consolidated proposal to exempt 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. 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 placed on the EU market before 22 July 2014. This article therefore does not apply to equipment placed on the market after this date. Recital (20) of RoHS 2 recall that as product reuse, refurbishment and extension of lifetime are beneficial, spare parts need to be available. According to the final report, the following technical information was discussed in public consultations and collected (for further information see footnote 4) as major aspects in the evaluation results:

– Refurbishment practices are well established (for imaging equipment such as magnetic resonance imaging devices, computer tomography devices, in-vitro diagnostic devices), beginning (patient monitoring devices), or generally in place (electron microscopes).

– Some of the reused spare parts will contain small amounts of lead, cadmium, hexavalent chromium, and/or PBDE.

– 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 reuse of spare parts.

– Existing exemption 31 does not allow for the use of spare parts recovered from used equipment which was not already placed on the EU market thus limiting the availability of reused spare parts for the repair and refurbishment of existing products in the EU market;

– 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

[4] Direct link to evaluation and recommendation:
http://rohs.exemptions.oeko.info/fileadmin/user_upload/ROHS_Pack5/201410_RoHS_Ex_Pack5_Final_Report_final.pdf (pages 26-55)
http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20150312_RoHS_scope_review_final_a.pdf (pages 70–104).

[5] http://ec.europa.eu/environment/waste/rohs_eee/studies_rohs1_en.htm.

would outweigh the positive impacts of restricting the reuse of recovered medical parts containing lead, cadmium, hexavalent chromium, and PBDE.

– 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.

With respect to a replacement of the existing exemption 31 in Annex IV with the following one "*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.",

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 thus justified. The proposed 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. Existing exemption 31 in Annex IV should be replaced with the proposed one.

In order to ensure a smooth transition for market operators from the old to the proposed provisions and to prevent single market disruptions, the provisions of this directive should be applied simultaneously by all Member States 18 months after the date of entry into force of this directive.

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, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in specific applications. The proposed act revokes the existing exemption 31 of RoHS 2 Annex IV; the exemption 31 of RoHS 2 Annex IV shall expire 18 months after the date of the decision.

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 adaptation 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.

COMMISSION DELEGATED DIRECTIVE (EU) .../…

of XXX

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[6], 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

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

their national provisions which also provides a reasonable period of time after the date of transposition

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 [*OP, please insert, as concrete date, the last day of the 9th month after entry into force of this directive*], 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 [*OP, please insert, as concrete date, 18 months after the date of entry into force of this directive*].

   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,

For the Commission
The President
[…]