COUNCIL OF THE EUROPEAN UNION

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	14 March 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2014) 1641 final
Subject:	Commission Delegated Directive ../…/EU of 13.3.2014 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 in micro-channel plates (MCPs)

Delegations will find attached document C(2014) 1641 final.

Encl.: C(2014) 1641 final

EUROPEAN
COMMISSION

Brussels, 13.3.2014
C(2014) 1641 final

COMMISSION DELEGATED DIRECTIVE ../…/EU

of 13.3.2014

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 in micro-channel plates (MCPs).

(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.

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 40 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.

Subsequently, the Commission consulted the official expert group for delegated acts under RoHS 2. A meeting with consultants and experts was held on 28 June 2013, a consolidated

[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 (pages 145-169).

recommendation with all necessary background information was sent out on 20 September 2013 and experts were invited to comment on the proposal by 15 November 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.

Technical background information (for further information see footnote 2):

Micro-channel plates (MCPs) are used for the detection and amplification of ions and electrons in medical devices and monitoring and control instruments. The substitution of lead in MCPs is scientifically and technically impracticable. The substitution of MCPs as components with alternative detectors is not viable under all possible conditions. Therefore granting an exemption for these identified cases where the performance and specific features of MCPs surpass alternative detectors would be in line with Article 5(1)(a), as the use of alternatives in these cases would be technically impracticable. The critical size and performance related conditions that require the use of MCPs (containing lead) are specified as criteria in the wording of the exemption.

As currently no lead-free alternatives are in sight, the exemption should be granted with the maximum validity period pursuant to Article 5(2) from the specific Article 4(3) compliance date. This would be 21 July 2021 for medical devices and monitoring and control instruments, 21 July 2023 for in-vitro medical devices, and 21 July 2024 for industrial monitoring and control instruments. In view of the relatively long innovation cycles and testing regimes for all medical devices and monitoring and control instruments in comparison to consumer products, 7 years is relatively short transition period which is unlikely to have adverse impacts on innovation.

The specific exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH).

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 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, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in micro-channel plates (MCPs).

(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 in electrical and electronic equipment placed on the market.

(2) Micro-channel plates (MCPs) are used for the detection and amplification of ions and electrons in medical devices and monitoring and control instruments. The substitution of lead in MCPs is scientifically and technically impracticable.

(3) The substitution of MCPs as components with alternative detectors is not viable under conditions where extreme miniaturisation, very short response times or very high signal multiplication factors are required. The use of lead in those cases where the performance and specific features of MCPs exceed alternative detectors should therefore be exempted from the prohibition. As currently no lead-free alternatives are in sight, pursuant to Article 5(2) of Directive 2011/65/EU, the validity period of the exemption should be 7 years from the relevant compliance dates for medical devices, monitoring and control instruments, in vitro medical devices and industrial monitoring and control instruments, as laid down in Article 4(3) of Directive 2011/65/EU. In view of the innovation cycles for all medical devices and monitoring and control instruments 7 years is a relatively short transition period which is unlikely to have adverse impacts on innovation.

(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, 13.3.2014

For the Commission
The President
José Manuel BARROSO