EUROPEAN
COMMISSION

Brussels, XXX
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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 mercury in intravascular ultrasound imaging systems

(Text with EEA relevance)

EN

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 mercury.

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, 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 list exemptions of materials and components from the substance restrictions under Article 4(1). 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 of RoHS 2 establishes a procedure for the adaptation of the Annexes to scientific and technical progress. RoHS 2 Article 5(1) 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 in accordance with 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 allow 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. With a view to evaluate the requested exemptions, the Commission commissioned several studies and carried out the requisite technical and scientific assessment including an official stakeholder consultation[2] for each application.[3] The final report, written by consultants Oeko Institute and approved by DG Environment, for this application is available on the consultants' webpage[4]; stakeholders and Member States were notified. The project page is accessible via the DG Environment webpage[5].

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1 OJ L 174, 1.7.2011, p. 88.

2 http://ec.europa.eu/environment/consultations/rohs7_en.htm; consultation period 19 August to 11 November 2013.

3 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.

4 Direct link to evaluation and recommendation: http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_IX/20140422_RoHS2_Evaluation_Ex_Requests_2013-1-5_final.pdf, pages 95-110.

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

Subsequently, the Commission consulted the official expert group for delegated acts under RoHS 2. A meeting with consultants and experts was held on 25 June 2014, a consolidated recommendation with all necessary background information was sent out on 1 July 2014 and experts were invited to comment on the proposal by 25 August 2014. The expert group unanimously supported the proposal to exempt mercury in intravascular ultrasound imaging systems. All necessary steps pursuant to Article 5(3) to (7) have been performed. Council and Parliament were notified of all activities.

According to the final report, the following technical information as discussed in public consultation was collected (for further information see footnote 4):

Mercury is used in electric rotating connectors in medical devices for intravascular ultrasound imaging. In such systems, a catheter is inserted into a patient's coronary artery. The transducer within the catheter must be rotated 360 degrees in order to scan around the entire artery. The use of mercury eliminates the noise generated by metal on metal contact under rotation, and supports the high peak power requirements for the device by increasing the metal contact area.

Based on current technology, substitution of mercury is not possible because it is the only conductive metal which is a liquid at room temperature. Any type of solid contact increases electrical resistance, decreases life through temperature build up and wear, introduces electrical noise through variation in resistance via mechanical non-uniformities, decreases bandwidth through introduction of resistance and limits power handling through the need to reduce surface area of the contact.

At present, the mercury component in the device cannot be replaced with a RoHS compliant component. Design alternatives such as the use of silver graphite or the use of rotary inductive couplers do not produce the same high quality performance as the mercury based device, which has unique capabilities that can have a positive impact on patients' health.

Both the substitution of mercury in electric rotating connectors in medical devices for intravascular ultrasound imaging and the elimination of mercury via substitution of the connector or the device are technically impracticable or have negative overall impacts due to an impact on patients' health.

In light of Article 5(1)(a) criteria one and three, an exemption is justified, and should be granted until mid-2019. In view of the relatively long innovation cycles for medical devices in comparison to consumer products this is a rather short transition period which is unlikely to have adverse impacts on innovation as no substitutes are available today or before the date of June 2019.

The specific exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH) in accordance with Article 5 of Directive 2011/65/EU.

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 mercury 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 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.

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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 mercury in electrical and electronic equipment placed on the market.

(2) Mercury is used in electric rotating connectors in medical devices for intravascular ultrasound imaging. Substitution of mercury or of the specific component would shorten product life or impair performance significantly.

(3) Both the substitution of mercury in the connector and the elimination of mercury via substitution of the connector or the device are technically impracticable or have negative overall impacts due to an impact on patients' health.

(4) The use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency modes of operation (> 50MHz) should therefore be exempted until 30 June 2019. In view of the innovation cycles for medical devices this is a short transition period which is unlikely to have adverse impacts on innovation.

(5) 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 ninth month after entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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

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
[…]