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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	30 January 2015
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2015) 328 final
Subject:	Commission Delegated Directive ../…/EU of 30.1.2015 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 polyvinyl chloride sensors in in-vitro diagnostic medical devices

Delegations will find attached document C(2015) 328 final.

Encl.: C(2015) 328 final

EUROPEAN
COMMISSION

Brussels, 30.1.2015
C(2015) 328 final

COMMISSION DELEGATED DIRECTIVE ../…/EU

of 30.1.2015

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 polyvinyl chloride sensors in in-vitro diagnostic medical devices

(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)[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

[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.

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 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 lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices until 31 December 2018. 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):

Blood, body fluid and body gas analysers serve as a critical analytical instrument across the EU and global health care sector. Blood testing is a core element to virtually all diagnostic and therapeutic procedures carried out in the health care sector today. Lead is used as a stabiliser for processing PVC which is used as base material in the sensor cards of the cartridges used in these critical care analysers. The PVC sensor card is the primary unit of the cartridge and represents a complicated and compact technological unit with an electrochemical process taking place during the testing.

Unlike alternatives such as tin, the lead in the sensor card does not interfere with the measurement of electrolytes. Although research of substitutes for lead to be used as a stabiliser in PVC sensor cards is ongoing, a suitable alternative is not yet available. Known metal based PVC stabilisers affect the performance while the research of non-metallic organic stabilisers will require more time. The performance of tested metal alternatives does not match technical requirements as it interferes with results. On the basis of the available information, substitution is technically impracticable for this specific application at present. The elimination of lead via the substitution of PVC in the sensor card is not yet possible, due to the heavy-duty product requirements for in-vitro diagnostics and the additional cost of substitution.

Both the substitution of lead in PVC sensor cards for in-vitro medical devices and the elimination of lead via substitution of PVC in these applications are technically impracticable.

In light of the first Article 5(1)(a) criterion, an exemption is justified, and should be granted until the end of 2018. 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 December 2018.

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.

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[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 27-39.

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

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 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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(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 in electrical and electronic equipment placed on the market.

(2) Blood, body fluid and body gas analysers serve as a critical analytical instrument in many diagnostic and therapeutic procedures. Lead is required as a stabiliser in the processing of the PVC for the sensor cards. Although research of substitutes is ongoing, a suitable alternative is not yet available. The performance of tested alternatives both to lead in PVC and to PVC itself does not meet the specific technical requirements.

(3) Both the substitution of lead in PVC sensor cards for in-vitro diagnostic medical devices for blood, body fluid and body gas analysis and the elimination of lead via substitution of PVC in these applications are technically impracticable.

(4) The use of lead in PVC sensors for blood, body fluid and body gas analysis used in in-vitro diagnostic medical devices should therefore be exempted until 31 December 2018. 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,

[6] 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 ninth 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, 30.1.2015

For the Commission
The President
Jean-Claude JUNCKER