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:	18 October 2013
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2013) 6835 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 in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators

Delegations will find attached document C(2013) 6835 final.

Encl.: C(2013) 6835 final

EUROPEAN
COMMISSION

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COMMISSION DELEGATED DIRECTIVE ../…/EU

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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 in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators

(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 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.

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

[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.

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.

With respect to the inclusion of an exemption for "lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators", 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. (Lead in solders in portable emergency defibrillators is already covered by exemption 17 in Annex IV of RoHS 2.)

Medical equipment must have high reliability as unexpected failures can be fatal. Many types of medical devices can be constructed using lead-free solders.

Some of the mobile medical devices are life-critical pieces of equipment that are transported in ambulances, helicopters or around hospitals. They may, therefore, suffer from high g impacts, severe vibration, high humidity and experience frequent large temperature changes. Tin/lead solder has been found to be reliable under these conditions. Lead-free solders are less likely to tolerate the severe strains on solder joints that can occur.

Medical devices are classified into classes I, IIa, IIb and III according to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. If class IIb products do not function due to a fault, there is a severe and immediate risk to the patient (i.e. irrevocable harm within minutes).

Unexpected faults with class IIa equipment can also have serious consequences although in general, these may not be as severe as for class IIb. However, there will be circumstances where defects or complete failure of class IIa equipment would be life threatening.

Therefore a temporary exemption to allow the continued use of lead solders is needed until further research has been carried out to identify alloys that are reliable for the normal life of mobile medical devices.

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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(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) Mobile medical devices are medical devices which are designed and approved by a notified body according to Directive 93/42/EEC to be hand carried, or to be transported on own wheels, on a cart or trolley or in a vehicle, aircraft or vessel during and/or between operations.

(3) Substitution or elimination of lead in the populated printed circuit boards of mobile medical devices is currently technically impracticable. A temporary exemption to allow the continued use of lead solders is needed until further research has been carried out to identify alloys that are reliable for the normal life of mobile medical devices.

(4) 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.

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

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 33 is added:

"33. Lead in solders on populated printed circuit boards used in Directive 93/42/EEC class IIa and IIb mobile medical devices other than portable emergency defibrillators. Expires on 30 June 2016 for class IIa and on 31 December 2020 for class IIb."