EUROPEAN
COMMISSION

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COMMISSION DELEGATED DIRECTIVE (EU) .../…

of XXX

amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as activator in the fluorescent powder of discharge lamps containing phosphors

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

This Commission Delegated Directive amends, for the purpose of adapting to technical progress, Annex III of Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)[1] (RoHS 2) as regards an exemption for specific applications containing lead.

RoHS 2 restricts the use of certain hazardous substances in electrical and electronic equipment, as provided for in its Article 4. It entered into force on 21 July 2011.

The restricted substances are listed in Annex II to RoHS 2. While the restrictions of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers are in force to date, the restrictions of bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), diisobutyl phthalate (DIBP) shall apply from 22 July 2019 or later. Annexes III and IV to RoHS 2 list the materials and components of electrical and electronic equipment (EEE) for specific applications exempted from the substance restriction of RoHS 2 Article 4(1).

Article 5 makes provision for the adaptation to scientific and technical progress (inclusion, renewal, amendments and revoking of exemptions) of Annexes III and IV. Pursuant to Article 5(1)(a), exemptions are to be included in Annexes III and IV only if such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006[2] 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.

Furthermore, 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 Article 20. Article 5(3) and Annex V establish the procedure for submitting applications for granting, renewing, or revoking an exemption.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Since the publication of RoHS 2, the Commission has received numerous[3] requests from economic operators, according to the provisions in Article 5(3) and Annex V, for both granting new and renewing existing exemptions.

The current Annex III exemption 18(b) permits the use of lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb). The Commission received two applications for renewal of this exemption in December 2014 and January 2015. While exemption 18(b) had 21 July 2016 as expiration date for categories 1 to 7 and 10[4], in line with the requirements

[1] OJ L 174, 1.7.2011, p. 88.
[2] OJ L 396, 30.12.2006, p. 1
[3] The list is given at: http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm
[4] These categories are namely: 1. Large household appliances; 2. Small household appliances; 3. IT and telecommunications equipment; 4. Consumer equipment; 5. Lighting equipment; 6. Electrical and

of the RoHS Directive (Article 5(5), second subparagraph), it continues to apply until a decision on the renewal application is taken by the Commission. Moreover, the Commission received in January 2015 a request no. 2015-3 for a new exemption to be added to Annex IV for discharge lamps when used as phototherapy lamps containing phosphors. As the assessment showed that it is mechanically possible that a lamp intended for medical use can fit in tanning equipment and vice versa, it was decided to merge these exemption requests under the assessment of exemption 18(b).

With a view to evaluating the application for exemption, the Commission launched a study to carry out the required technical and scientific assessment, including an eight-week online open-ended stakeholder consultation[5] on the application. One contribution was made to the stakeholder consultation.

The final report containing the assessment of the application was published[6]; stakeholders were notified.

Subsequently, the Commission consulted the Member States expert group for delegated acts under RoHS 2 during an expert meeting on 15 December 2016, which also involved presentations from the applicants and stakeholders most concerned. The experts agreed with the draft presented by the Commission, with a large majority of absent or silent members. In accordance with the Better Regulation Guidelines, the draft Delegated Directive was published on the Better Regulation Portal for a four-week public feedback period. Two comments were received, both addressing the issue of categories applicable to the wording of the draft Delegated Directive. The comments were taken into account and the draft Delegated Directive was correspondingly amended. All necessary steps relating to exemptions from the substance restriction pursuant to Articles 5(3) to 5(7) have been performed.[7] The Council and the European Parliament were notified of all activities.

The final report highlighted in particular the following technical information and assessment:

- Lead activator in the fluorescent powder is required to allow the barium silicate phosphor to fluoresce. It transforms the 254 nm radiation to the designed UV (290nm-400nm) radiation and it is used in over 95% of the indoor low pressure mercury vapour fluorescent lamps in tanning and certain medical applications. It provides UV intensity at the wavelength of 350 nm that is crucial in order to initiate skin pigmentation (tanning result).
- Tanning equipment is strictly regulated in the EU and any possible alternative to lead would have to fulfil criteria on reliability, safety and health risk concerns. Currently, there are no such alternatives available and the substitution of lead hence is scientifically and technically impracticable.

The evaluation results for category 1 to 7 and 10 show the specific exemption is consistent with Regulation (EC) No 1907/2006 (REACH) and thus does not weaken the environmental and health protection afforded by it, in accordance with Article 5 of Directive 2011/65/EU. Furthermore, at least one of the relevant criteria specified in Article 5(1)(a) is met by the

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electronic tools; 7. Toys, leisure and sports equipment; 10. Automatic dispensers. EEE categories are listed in Annex I to the RoHS Directive.

5 Consultation period: from 21.08.2015 to 16.10.2015

6 https://bookshop.europa.eu/en/assistance-to-the-commission-on-technological-socio-economic-and-cost-benefit-assessment-related-to-exemptions-from-the-substance-restrictions-in-electrical-and-electronic-equipment-pbKH0416554/

7 A list of the required administrative steps is available on the Commission website. Current stage of the procedure can be viewed for each draft delegated act in the Interinstitutional Registry of Delegated Acts at https://webgate.ec.europa.eu/regdel/#/home.

exemption request relating to entry 18(b) in Annex III. Since for the applications concerned, no sufficiently reliable alternatives are available today or are likely to come on the market soon, validity period until 21 July 2021 is justified; as reliable substitutes are not yet available, no negative socioeconomic impacts of substitution are to be anticipated for this period. The granted validity period is also not expected to have adverse impacts on innovation. Furthermore, in view of request no. 2015-3 and the fact that it is mechanically possible that a lamp intended for medical or tanning use can fit in the same luminaire or equipment, a new sub-entry to the exemption 18(b) specific to medical applications (except those covered under point 34 of Annex IV) shall be added.

For categories other than categories 1 to 7 and 10, the existing exemption remains as per the validity periods set out in Article 5(2).

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Delegated Directive grants an exemption from the restrictions in Article 4(1), to be listed in Annex III of Directive 2011/65/EU, for the use of lead in specific applications.

The instrument is a Delegated Directive, as provided for by Directive 2011/65/EU, and in particular meeting the relevant requirements of Article 5(1)(a) thereof.

The objective of the Delegated Directive is to contribute to the protection of human health and the environment and approximate the provisions for the functioning of the internal market in the field of electrical and electronic equipment, by allowing the use of otherwise banned substances for specific applications, in line with the provisions and under the conditions of RoHS 2 and the therein established procedure for the adaptation of the Annexes III and IV 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 scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as activator in the fluorescent powder of discharge lamps containing phosphors

(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[1] and in particular Article 5(1)(a) thereof,

Whereas:

(1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain certain hazardous substances listed in Annex II to that Directive. That requirement does not apply to the applications listed in Annex III to Directive 2011/65/EU.

(2) The different categories of electrical and electronic equipment for which Directive 2011/65/EU applies are listed in Annex I to that Directive.

(3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU. The use of lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors such as BSP (BaSi2O5:Pb) was, however, exempted from the restriction and is as such currently listed in entry 18(b) of Annex III to that Directive. The original expiry date of that exemption was, for categories 1 to 7 and 10, 21 July 2016, in accordance with the second subparagraph of Article 5(2) of that Directive.

(4) The Commission received an application for renewal of that exemption before 21 January 2015, in accordance with the first subparagraph of Article 5(5) of Directive 2011/65/EU. That exemption remains valid until a decision on that application has been adopted, in accordance with the second subparagraph of that Article.

(5) Moreover, the Commission received in January 2015 a request no. 2015-3 for a new exemption to be added to Annex IV for discharge lamps when used as phototherapy lamps (medical equipment) containing phosphors. As the assessment showed that it is mechanically possible that a lamp intended for medical use can fit in tanning equipment and vice versa, it was decided to merge these exemption requests under the assessment of exemption under entry 18(b) in Annex III.

(6) Lead activator in the fluorescent powder is required to allow the barium silicate phosphor to fluoresce. It transforms the 254 nm radiation to the designed UV (290nm-

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

400nm) radiation and it is used in over 95% of the indoor low pressure mercury vapour fluorescent lamps in tanning and certain medical applications. It provides UV intensity at the wavelength of 350 nm that is crucial in order to initiate skin pigmentation.

(7) Tanning equipment is strictly regulated in the Union and any possible alternative to lead would have to fulfil criteria on reliability, safety and health risk concerns. Currently, there are no such alternatives available.

(8) Due to the lack of reliable substitutes, a substitution or elimination of lead is still scientifically and technically impracticable for certain discharge lamps containing phosphors. The exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[2] and thus does not weaken the environmental and health protection afforded by it. The exemption for the use of lead as activator in the fluorescent powder (1% lead by weight or less) of discharge lamps when used as sun tanning lamps containing phosphors should therefore be renewed.

(9) Since, for the applications concerned, no reliable alternatives are yet available on the market, the exemption for categories 1 to 7 and 10 of Annex I to Directive 2011/65/EU should be renewed for the maximum validity period of five years until 21 July 2021. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

(10) For categories other than 1 to 7 and 10 of Annex I to Directive 2011/65/EU, the existing exemption remains valid as per the validity periods set out in the second subparagraph of Article 5(2) of Directive 2011/65/EU. For reasons of legal clarity, the dates of expiry should be specified in Annex III to that Directive.

(11) In view of request no. 2015-3 and the fact that it is mechanically possible for a lamp intended for medical use to fit in tanning equipment and vice versa, a new sub-entry 18(b)-I should be added in Annex III to Directive 2011/65/EU specific to medical applications with the exception of those covered by entry 34 of Annex IV to Directive 2011/65/EU. This sub-entry should apply to categories 5 and 8 and be valid until 21 July 2021.

(12) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III 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 [the last day of the 12th month after the date of entry into force of this Directive] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

They shall apply those provisions from [the last day of the 12th month after the date of entry into force of this Directive + 1 day].

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
[…]