



Brussels, **XXX**  
[...] (2019) **XXX** draft

**COMMISSION DELEGATED DIRECTIVE (EU) .../...**

**of **XXX****

**amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in platinized platinum electrodes used for certain conductivity measurements**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

This Commission Delegated Directive amends, for the purpose of adapting to technical progress, Annex IV 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)<sup>1</sup> (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 currently restricted substances as listed in Annex II to RoHS 2 are the following: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP). 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<sup>2</sup> 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<sup>3</sup> 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 IV exemption 37 permits the use of lead in platinized platinum electrodes used for conductivity measurements where certain conditions apply. The Commission received one application for renewal of this exemption in June 2017. While exemption 37 had 31 December 2018 as expiration date for categories 8 and 9, in line with the requirements of

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<sup>1</sup> OJ L 174, 1.7.2011, p. 88.

<sup>2</sup> OJ L 396, 30.12.2006, p. 1.

<sup>3</sup> The list is given at: [http://ec.europa.eu/environment/waste/rohs\\_eee/adaptation\\_en.htm](http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm)

the RoHS Directive (Article 5(5), second subparagraph), it continues to apply until a decision on the renewal application is taken by the Commission.<sup>4</sup>

With a view to evaluating the request for exemption, the Commission launched a study to carry out the required technical and scientific assessment, including a six-week online open-ended stakeholder consultation<sup>5</sup> on the application. No contributions were received during the stakeholder consultation.

The final report containing the assessment of the application was published<sup>6</sup>; stakeholders were notified.

Subsequently, the Commission consulted the Member States expert group for delegated acts under RoHS 2 during an expert meeting on 29 October 2018. The experts agreed with the proposal presented, with a large majority of absent or silent members. All applicable steps relating to exemptions from the substance restriction pursuant to Articles 5(3) to 5(7) have been performed.<sup>7</sup> The Council and the European Parliament were notified of all activities.

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

- Lead-containing platinized platinum electrodes are used in specialised instruments for measurements which require certain measurement qualities such as wide range, high accuracy, or high reliability for high concentration of acid and alkali. The electrodes are applied among others in electrical conductivity meters used for inspecting and testing of water (river waters, seawater, drinking water, industrial effluents etc.).
- Currently, a substitution or elimination of lead in the applications concerned is still scientifically and technically impracticable.

The evaluation results for categories 8 and 9 show the specific exemption would 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. Furthermore, at least one of the relevant criteria specified in Article 5(1)(a) is met by the exemption request: Since for the applications concerned, no reliable alternatives are available today or are likely to come on the market soon, a renewal of the exemption for the maximum period of seven years until 31 December 2025 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.

### 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 IV of Directive 2011/65/EU, for the use of lead in specific applications.

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<sup>4</sup> The categories listed in Annex I of Directive 2011/65/EU are namely: 1. Large household appliances; 2. Small household appliances; 3. IT and telecommunications equipment; 4. Consumer equipment; 5. Lighting equipment; 6. Electrical and electronic tools; 7. Toys, leisure and sports equipment; 8. Medical devices; 9. Monitoring and control instruments including industrial monitoring and control instruments; 10. Automatic dispensers; 11. Other EEE not covered by any of the categories above.

<sup>5</sup> [Consultation period](#): from 20.10.2017 to 01.12.2017.

<sup>6</sup> <https://publications.europa.eu/en/publication-detail/-/publication/33a336f0-e0ef-11e8-b690-01aa75ed71a1/language-en/format-PDF/source-85019010>.

<sup>7</sup> 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>.

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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(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<sup>1</sup>, 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 the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications which are specific to medical devices and monitoring and control instruments and are listed in Annex IV to that Directive.
- (2) The categories of electrical and electronic equipment to 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.
- (4) By Delegated Directive 2014/73/EU<sup>2</sup>, the Commission granted an exemption for the use of lead in platinized platinum electrodes used for conductivity measurements where certain conditions apply (“the exemption”), by including the relevant applications in Annex IV to Directive 2011/65/EU. The exemption was to expire on 31 December 2018, in accordance with the third subparagraph of Article 5(2) of that Directive.
- (5) The Commission received an application for renewal of the exemption (“the renewal request”) on 30 June 2017, that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.
- (6) The evaluation of the renewal request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

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<sup>1</sup> OJ L 174, 1.7.2011, p. 88.

<sup>2</sup> Commission Delegated Directive 2014/73/EU of 13 March 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 platinized platinum electrodes used for conductivity measurements (OJ L 148, 20.5.2014, p. 80).

- (7) Lead-containing platinized platinum electrodes are used in specialised instruments for measurements which require certain measurement qualities such as wide range, high accuracy, or high reliability for high concentration of acid and alkali.
- (8) Due to the lack of reliable alternatives, a substitution or elimination of lead in the applications concerned is currently scientifically and technically impracticable for certain measurement instruments. The renewal of the exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>3</sup> and thus does not weaken the environmental and health protection afforded by it.
- (9) It is, therefore, appropriate to grant the renewal of the exemption.
- (10) The exemption should be renewed for the maximum duration of 7 years until 31 December 2025, in accordance with Article 4(3) and the third subparagraph of Article 5(2) of Directive 2011/65/EU. 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.
- (11) 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 adopt and publish, by [\[the last day of the 12<sup>th</sup> month after the date of entry into force of this Directive\]](#) 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.

They shall apply those provisions from [\[the last day of the 12<sup>th</sup> month after the date of entry into force of this Directive + 1 day\]](#).

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.

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<sup>3</sup> 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).

Done at Brussels,

*For the Commission*  
*The President*  
[\[...\]](#)



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ANNEX

ANNEX

to

**Commission Delegated Directive**

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## ANNEX

In Annex IV to Directive 2011/65/EU, entry 37 is replaced by the following:

- "37. Lead in platinized platinum electrodes used for conductivity measurements where at least one of the following conditions applies:
- (a) wide-range measurements with a conductivity range covering more than 1 order of magnitude (e.g. range between 0,1 mS/m and 5 mS/m) in laboratory applications for unknown concentrations;
  - (b) measurements of solutions where an accuracy of  $\pm 1\%$  of the sample range and where high corrosion resistance of the electrode are required for any of the following:
    - (i) solutions with an acidity  $< \text{pH } 1$ ;
    - (ii) solutions with an alkalinity  $> \text{pH } 13$ ;
    - (iii) corrosive solutions containing halogen gas;
  - (c) measurements of conductivities above 100 mS/m that must be performed with portable instruments.

Expires on 31 December 2025."