



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

**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 in solders and termination finishes used in certain hand-held  
combustion engines**

(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 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)<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 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<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 III exemption 41 permits the use of lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council). The Commission received one application for renewal of this

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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)

exemption in June 2017 for categories 6 and 11. While exemption 41 had 31 December 2018 as expiration date for categories 1 to 7 and 10, in line with the requirements 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.<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 is a common alloying element in solder material to control the melting point. The applicant has successfully tested alternative materials to replace the restricted substance. However, additional time is needed to confirm the reliability of the lead-free products.
- Currently, the reliability of lead-free alternatives available on the market is still to be confirmed in further testing.

The evaluation results for categories 1 to 7, 10 and 11 show that 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, granting the exemption with a validity period of 24 months after the publication of the delegated directive in the Official Journal 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.

For categories 8 and 9, the existing exemption remains as per the validity periods set out in Article 5(2).

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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>.

### **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.

# 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 in solders and termination finishes used in certain hand-held combustion engines**

(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 the exempted applications listed in Annex III to Directive 2011/65/EU.
- (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 (EU) 2014/72/EU<sup>2</sup>, the Commission granted an exemption for the use of lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council<sup>3</sup>) (“the exemption”) by including those applications in Annex III to Directive 2011/65/EU. The exemption was to expire for categories 1 to 7 and 10 on 31

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

<sup>2</sup> Commission Delegated Directive 2014/72/EU of 13 March 2014 amending, for the purposes of adapting to technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems (OJ L 148, 20.5.2014, p. 78).

<sup>3</sup> Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p.1). Directive 97/68/EC has been repealed by Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

December 2018, in accordance with the second subparagraph of Article 5(2) of that Directive.

- (5) The Commission received an application for renewal of the exemption for categories 6 and 11 (“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.
- (7) Lead is a common alloying element in solder material to control the melting point. Alternative materials to replace the restricted substance have been successfully tested. However, additional time is needed to confirm the reliability of the lead-free products.
- (8) Currently, there are no lead-free alternatives available on the market which would provide sufficient level of reliability for the applications covered by the exemption.
- (9) Due to the lack of reliable alternatives, a substitution or elimination of lead is currently scientifically and technically impracticable for certain hand-held combustion engines. It is, therefore, appropriate, to renew the exemption. The renewal of the exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>4</sup> and thus does not weaken the environmental and health protection afforded by it.
- (10) The exemption for categories 1 to 7, 10 and 11 should be renewed until [\[the last day of the 24<sup>th</sup> month after the publication of this Directive in the Official Journal\]](#), in accordance with Article 4(3) and the first 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) For categories 8 and 9, 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.
- (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 [\[the last day of the 12<sup>th</sup> month after the date of entry into force of this Directive\]](#) 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.

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<sup>4</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).

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.

Done at Brussels,

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



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

ANNEX

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to

**Commission Delegated Directive**

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## ANNEX

In Annex III to Directive 2011/65/EU, entry 41 is replaced by the following:

"41	Lead in solders and termination finishes of electrical and electronic components and finishes of printed circuit boards used in ignition modules and other electrical and electronic engine control systems, which for technical reasons must be mounted directly on or in the crankcase or cylinder of hand-held combustion engines (classes SH:1, SH:2, SH:3 of Directive 97/68/EC of the European Parliament and of the Council *)	Applies to all categories and expires on: <ul style="list-style-type: none"><li>– [the last day of the 24<sup>th</sup> month after the publication of this Delegated Directive in the Official Journal] for categories 1 to 7, 10 and 11;</li><li>– 21 July 2021 for categories 8 and 9 other than in vitro diagnostic medical devices and industrial monitoring and control instruments;</li><li>– 21 July 2023 for category 8 in vitro diagnostic medical devices;</li><li>– 21 July 2024 for category 9 industrial monitoring and control instruments."</li></ul>
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\* Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery (OJ L 59, 27.2.1998, p. 1).