

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 used in certain combustion engines**

(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)<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 Commission received a request for a new exemption to Annex III for use of lead in solders of sensors, actuators and engine control units (ECUs) that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal

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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)

combustion engines used in equipment that are not intended to be used solely by consumers on 29 June 2017 (request no. 2017-7). The exemption was requested for category 11<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. One contribution was 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 clarity of the proposed wording for this exemption was discussed by the experts. The recommended wording was subsequently amended; in particular, the word "solder" was added to the text. The experts agreed with the amended proposal presented, with a large majority of 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:

- The conditions experienced in and close to an engine and exhaust in scope of the requested exemption can be very severe with elevated temperatures and vibration levels that may cause early failure of solder bonds. Each engine is designed with specific types of sensors (as well as actuators and ECUs) that have to be thoroughly tested to ensure that they will be reliable and the engines will meet the emissions limits as per Regulation (EU) 2016/1628 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery.
- Currently, for applications concerned, additional time is needed for testing to ensure the reliability of available lead-free alternatives.

The evaluation results for category 11 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, granting the exemption with the maximum validity period of five years, starting from 22 July 2019<sup>8</sup>, is justified. As reliable substitutes are not yet available, no negative

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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/0814e920-4c55-11e9-a8ed-01aa75ed71a1/language-en>.

<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>.

<sup>8</sup> Restrictions set out by Directive 2011/65/EU will become applicable to category 11 on 22 July 2019. The exemption validity period for category 11 is specified in Article 5(2) of that Directive.

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 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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(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 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 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. On 29 June 2017, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption to be listed in Annex III to Directive 2011/65/EU, for the use of lead in solders of sensors, actuators and engine control units that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal combustion engines used in equipment that are not intended to be used solely by consumers (“the requested exemption”).
- (4) The evaluation of the requested exemption included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.
- (4) Each engine within scope of the requested exemption is equipped with specific types of sensors, actuators and engine control units that monitor and control its emissions to ensure compliance with Regulation (EU) 2016/1628 of the European Parliament and of the Council<sup>2</sup>. The conditions experienced in and close to such engine and an exhaust system can be so severe in terms of elevated temperatures and vibration levels that they may cause early failure of solder bonds.

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

<sup>2</sup> 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).

- (5) Currently, for the applications of lead covered by the requested exemption, additional time is needed for testing to ensure the reliability of available lead-free substitutes.
- (6) Due to the lack of reliable alternatives, a substitution or elimination of lead is scientifically and technically impracticable in certain combustion engines. The requested 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.
- (6) It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex III to Directive 2011/65/EU with respect to electrical and electronic equipment of category 11 of Annex I to Directive 2011/65/EU.
- (7) The exemption should be granted for the maximum validity period of 5 years starting from 22 July 2019, 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.
- (8) 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.

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*.

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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).

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels,

*For the Commission*

*The President*

*[...]*

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ANNEX

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to

**Commission Delegated Directive**

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## ANNEX

In Annex III to Directive 2011/65/EU, the following entry 44 is added:

"44	Lead in solder of sensors, actuators, and engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of the European Parliament and of the Council*, installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users	Applies to category 11 and expires on 21 July 2024.
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\* 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)."