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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Subject:	COMMISSION DELEGATED DIRECTIVE (EU) .../... of 8.8.2019 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 bis(2-ethylhexyl) phthalate (DEHP) in certain rubber components used in engine systems

Delegations will find attached document C(2019) 5780 final.

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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 bis(2-ethylhexyl) phthalate (DEHP) in certain rubber components used in engine systems

(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)¹ (RoHS 2) as regards an exemption for specific applications containing bis(2-ethylhexyl) phthalate (DEHP).

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 1907/2006² 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 numerous³ 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 DEHP in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed

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

for use in equipment that is not designed solely for consumer use on 29 June 2017 (request no. 2017-6). The exemption was requested for category 11⁴.

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 consultation⁵ on the application. One contribution was received during the stakeholder consultation.

The final report containing the assessment of the application was published⁶; 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 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. No comments were received. All applicable 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:

- DEHP is added to rubber material as plasticiser in order to provide flexibility. The rubber components are used as flexible connections between parts of engine systems and assure prevention of leakage, sealing of engine parts and protection from vibration or dirt and fluids over the long lifetime of the engines.
- While substitution of DEHP is in principle scientifically and technically viable in some rubber components, the reliability of these substitutes still needs to be ensured for the specific uses in the engine systems in scope of this requested exemption, where long lifetime and special requirements such as resistance to any contact material (e.g. fuel, lubricant oil, coolants, gases, dirt), temperature and vibration are required.

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 2019⁸, is justified. As reliable substitutes are not yet available, no negative

⁴ 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.

⁵ [Consultation period](#): from 20.10.2017 to 01.12.2017.

⁶ <https://publications.europa.eu/en/publication-detail/-/publication/0814e920-4c55-11e9-a8ed-01aa75ed71a1/language-en>.

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>.

⁸ 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 DEHP 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 8.8.2019

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 bis(2-ethylhexyl) phthalate (DEHP) in certain rubber components used in engine systems

(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 equipment¹ 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) Bis(2-ethylhexyl) phthalate (DEHP) 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 that Directive, for the use of DEHP in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed for use in equipment that is not designed solely for consumer use (“the requested exemption”).
- (4) The evaluation of the requested exemption included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.
- (5) DEHP is added to rubber material as plasticiser in order to provide flexibility. The rubber components are used as flexible connections between parts of engine systems and assure prevention of leakage, sealing of engine parts and protection from vibration or dirt and fluids over the lifetime of the engines.
- (6) Currently, there are no DEHP-free alternatives available on the market which would provide sufficient level of reliability for applications in engines where long life and special properties such as resistance to any contact material (e.g. fuel, lubricant oil, coolants, gases, or dirt), temperature and vibration are required.

¹ OJ L 174, 1.7.2011, p. 88.

- (7) Due to the lack of reliable alternatives, a substitution or elimination of DEHP is still scientifically and technically impracticable for certain rubber parts used in engine systems. The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council² and thus does not weaken the environmental and health protection afforded by it.
- (8) 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.
- (9) 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.
- (10) 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 5th 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 5th 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*.

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).

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8.8.2019

For the Commission
The President
Jean-Claude JUNCKER