

Commission Delegated Directive (EU) 2019/1845 of 8 August 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)

COMMISSION DELEGATED DIRECTIVE (EU) 2019/1845

of 8 August 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 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) 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.
- (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 Council<sup>(2)</sup> 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 30 April 2020 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 1 May 2020.

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, 8 August 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER

## ANNEX

In Annex III to Directive 2011/65/EU, the following entry 43 is added:

43	<p>Bis(2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use and provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin and the concentration value of bis(2-ethylhexyl) phthalate does not exceed:</p> <p>(a) 30 % by weight of the rubber for</p> <p>(i) gasket coatings;</p> <p>(ii) solid-rubber gaskets; or</p> <p>(iii) rubber components included in assemblies of at least three components using electrical, mechanical or hydraulic energy to do work, and attached to the engine.</p> <p>(b) 10 % by weight of the rubber for rubber-containing components not referred to in point (a).</p> <p>For the purposes of this entry, “prolonged contact with human skin” means</p>	Applies to category 11 and expires on 21 July 2024.
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**Status:** This is the original version (as it was originally adopted).

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continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.
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- (1) [OJ L 174, 1.7.2011, p. 88.](#)
- (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.](#))