

Commission Delegated Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (Text with EEA relevance)

COMMISSION DELEGATED DIRECTIVE (EU) 2015/863

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amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

(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,⁽¹⁾ and in particular Article 6(3) thereof,

Whereas:

- (1) Directive 2011/65/EU lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.
- (2) Directive 2011/65/EU prohibits the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in electrical and electronic equipment placed on the Union market. Annex II to that Directive lists those restricted substances.
- (3) The risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered a priority in the periodic review of the list of restricted substances in Annex II. With a view to further restrictions, the substances that were subject to previous assessments should be re-investigated.
- (4) In accordance with Article 6(1) of Directive 2011/65/EU, interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations, have been consulted and a thorough assessment has been performed.
- (5) Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) are substances of very high concern (SVHC). DIBP is a substance that can be used as a substitute for DBP and was subject to previous assessments performed by the Commission. The available evidence indicates that those

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four substances, when used in EEE, can have a negative impact on recycling and on human health and the environment during EEE waste management operations.

- (6) Substitutes that have less negative impacts are available for DEHP, BBP, DBP and DIBP in most EEE. The use of those substances in EEE should therefore be restricted. DEHP, BBP and DBP are already restricted through entry 51 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council,⁽²⁾ so that toys containing DEHP, BBP or DBP in a concentration greater than 0,1 % by weight of the plasticised material, calculated for the three phthalates cumulatively, cannot be placed on the EU market. In order to avoid double regulation, the restriction through entry 51 of Annex XVII to that Regulation shall therefore continue to be the only restriction applicable to DEHP, BBP and DBP in toys.
- (7) In order to facilitate transition and to mitigate possible socioeconomic impacts, an appropriate transition period should be granted, which will allow economic operators to apply for exemptions from the substance restrictions in accordance with Article 5 of Directive 2011/65/EU. The longer innovation cycles for medical devices and monitoring and control instruments should be taken into account while determining the transitional period. The restriction of the use of DEHP, BBP, DBP and DIBP should therefore apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.
- (8) Any adaptation of Annex III or IV to Directive 2011/65/EU to exempt applications in relation to DEHP or DBP should take place in a manner which, in order to avoid double regulation and unnecessary burden, ensures coherence with the administration of any authorisation granted under Regulation (EC) No 1907/2006 in relation to the incorporation of those substances in EEE. Operators considering whether to apply for exemptions under Directive 2011/65/EU should be aware that such exemptions may cover the entire life cycle of the EEE, including the manufacturing phase.
- (9) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2011/65/EU is replaced by the text in the Annex to this Directive.

Article 2

1 Member States shall adopt and publish, by 31 December 2016 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 22 July 2019.

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.

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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, 31 March 2015.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

ANNEX II

Restricted substances referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials

- Lead (0,1 %)
- Mercury (0,1 %)
- Cadmium (0,01 %)
- Hexavalent chromium (0,1 %)
- Polybrominated biphenyls (PBB) (0,1 %)
- Polybrominated diphenyl ethers (PBDE) (0,1 %)
- Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)
- Butyl benzyl phthalate (BBP) (0,1 %)
- Dibutyl phthalate (DBP) (0,1 %)
- Diisobutyl phthalate (DIBP) (0,1 %)

The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021.

The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.

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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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([OJ L 396, 30.12.2006, p. 1](#)).