

COMMISSION DELEGATED DIRECTIVE (EU) 2021/1980**of 11 August 2021****amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids****(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 5(1), point (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 the Directive. That restriction does not apply to certain exempted applications listed in Annex IV to the Directive.
- (2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in its Annex I.
- (3) Pursuant to Commission Delegated Directive (EU) 2015/863 ⁽²⁾, bis(2-ethylhexyl) phthalate (DEHP) is a restricted substance listed in Annex II to Directive 2011/65/EU and its use is to be prohibited, from 22 July 2021, in medical devices, including *in vitro* medical devices above a maximum concentration value of 0,1% tolerated by weight in homogeneous materials.
- (4) On 17 July 2018, 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 IV to that Directive, for the use of DEHP in ion selective electrodes for analysing human body fluids and/or in dialysate fluids ('the requested exemption').
- (5) DEHP is used as a membrane solvent of ion selective electrodes applied in point of care analysers which help to measure the concentration of ionic substances in human body fluids and/or in dialysate fluids.
- (6) A technical and scientific assessment study was carried out to evaluate the exemption application ⁽³⁾. The evaluation of the application concluded that alternatives to DEHP are currently not sufficiently reliable and that the substitution of DEHP in specific applications would result in negative environmental and health impacts that outweigh its benefits. The evaluation included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU. The comments received during those consultations were made publicly available on a dedicated website.

⁽¹⁾ OJ L 174, 1.7.2011, p. 88.

⁽²⁾ 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 (OJ L 137, 4.6.2015, p. 10).

⁽³⁾ Study to assess three exemption requests relating to Annex IV to Directive 2011/65/EU (Pack 17).

- (7) The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁴⁾ 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 IV to Directive 2011/65/EU.
- (9) To provide efficient technical equipment for health services and to allow time for the development of suitable alternatives, the requested exemption should be granted for a duration of 7 years starting from the date of application of this Directive in accordance with Article 5(2), first subparagraph, 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.
- (11) In the interest of legal certainty and in order to protect the legitimate expectations of operators supplying the medical devices concerned that the requested exemption applies by the date of entry into force of the prohibition for the use of the restricted substance in question, and in the absence of any legitimate interest in creating a disruption to the supply of those medical devices as a result of the entry into force of that prohibition, this Directive should enter into force as a matter of urgency and should apply with retroactive effect from 21 July 2021,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV 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 2022 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall communicate the text of those provisions to the Commission forthwith.

They shall apply those provisions from 21 July 2021.

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 that they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

⁽⁴⁾ 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).

Done at Brussels, 11 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex IV to Directive 2011/65/EU, the following entry 45 is added:

'45 Bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids

Expires on 21 July 2028.'
