EUROPEAN
COMMISSION

Brussels, XXX
[…](2021) XXX draft

**COMMISSION DELEGATED DIRECTIVE (EU) .../…**

**of XXX**

**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 in dialysate fluids**

# EXPLANATORY MEMORANDUM

## 1. CONTEXT OF THE DELEGATED ACT

This Commission Delegated Directive amends, for the purpose of adapting to technical and scientific progress, Annex IV to 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] (the RoHS Directive) as regards an exemption for specific applications containing bis(2-ethylhexyl) phthalate (DEHP).

Article 4 of the RoHS Directive restricts the use of certain hazardous substances in electrical and electronic equipment (EEE). Currently, 10 substances are restricted and listed in Annex II to the Directive: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP). DEHP was added to the list by Commission Delegated Directive (EU) 2015/863[2] and will be prohibited in medical devices covered by the RoHS Directive from 22 July 2021.

Annexes III and IV to the RoHS Directive list the materials and components of EEE for specific applications exempted from the substance restrictions in its Article 4(1). Article 5 provides for Annexes III and IV to be adapted to scientific and technical progress (as regards the granting, renewing and revoking of exemptions). Under Article 5(1)(a), exemptions are to be included in Annexes III and IV only if this does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 (REACH)[3] and any of the following conditions is fulfilled:

– their elimination or substitution via design changes or materials and components that 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;

– the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits.

Decisions on exemptions, and their duration, are to take into account the availability of substitutes and the socio-economic impact of substitution. Decisions on the duration of exemptions must take into account any potential impact on innovation. Life-cycle thinking on the overall impacts of the exemption must apply, where relevant.

Article 5(1) of the RoHS Directive provides for the Commission to include materials and components of EEE for specific applications in the lists in Annexes III and IV by means of individual delegated acts pursuant to Article 20. Article 5(3) and Annex V establish the procedure for submitting exemption applications.

---

1 OJ L 174, 1.7.2011, p. 88.

2 OJ L 137, 4.6.2015, p. 10.

3 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).

## 2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission receives numerous requests[4] from economic operators to grant or renew exemptions under the RoHS Directive (Article 5(3) and Annex V).

On 17 July 2018, the Commission received a request for a new exemption in Annex IV to allow the placing on the market of medical devices containing >0.1% DEHP by weight in homogeneous materials in specific applications. The request concerns an exemption for the use of DEHP in ion-selective electrodes applied in point of care analysis for medical devices.

In November 2018, in order to evaluate the application for this new exemption, the Commission launched a study[5] to carry out the required technical and scientific assessment. The study, which was concluded in 2020, involved an 8-week online stakeholder consultation, during which one contribution was received. Information concerning the consultation was provided on the project website[6].

The Commission consulted the Member States' expert group for delegated acts under the RoHS Directive on 23 February 2021. Some experts expressed agreement with the drafts presented, with a large group remaining silent. The Commission has taken all necessary steps relating to exemptions from the substance restriction pursuant to Article 5(3) to (7)[7]. It notified the Council and the European Parliament of all activities in this context.

The technical and scientific assessment report highlighted that:

- DEHP is used in membrane solvent for ion-selective electrode constituents in analysers that allow the practicable and quick 'point of care analysis' of ionic substances present in human body fluids and/or in dialysate fluids;
- it would be technically feasible to substitute the membrane solvent, but current alternatives are not performing well and may *inter alia* have adverse socio-economic impacts;
- not granting the exemption would result in the early obsolescence of around 500 t of point of care analysers that depend on ion-selective electrodes. The environmental benefit of not placing DEHP membrane solvents on the market is relatively limited, as spent ion-selective electrodes are medical waste and ultimately incinerated. The DEHP would not be returned to the material cycle;
- not granting an exemption would also place a high financial and organisational burden on healthcare facilities as a result of having to replace the point of care analysers. This could prevent or delay analyses and the health service might have to finance unplanned new equipment, resulting in unintended indirect health impacts;
- overall, the total negative environmental and health impacts of substituting DEHP in ion-selective electrode constituents are likely to outweigh the total benefits;
- in the light of the average lifetime of ion-selective electrode point of care analysers and the likely time required for switching to a non-DEHP market, the maximum 7-year

[4] http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm.

[5] For the final report of the study (Pack 17), see: https://op.europa.eu/en/publication-detail/-/publication/df0ab036-8b52-11ea-812f-01aa75ed71a1/language-en/format-PDF/source-146143357.

[6] Consultation period: 18 March to 17 May 2019; https://rohs.exemptions.oeko.info/.

[7] A list of the required administrative steps is available on the Commission website. The 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.

exemption period, as laid down in Article 5(2) of the RoHS Directive, is appropriate for these specific applications.

## 3. LEGAL ELEMENTS OF THE DELEGATED ACT

While DEHP in articles is restricted by entry 51 in Annex XVII to the REACH Regulation, EEE within the scope of the RoHS Directive is exempted from that restriction. The evaluation results show that granting the exemption would not weaken the environmental and health protection afforded by REACH, thereby satisfying the condition in Article 5 of the Directive.

Furthermore, the exemption request meets at least one of the criteria in Article 5(1)(a) of the Directive: overall, the reliability of substitutes is currently not sufficiently ensured and 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.

The validity period of the exemption is not expected to have adverse impacts on innovation. Therefore, the exemption should be granted for a period of 7 years.

The proposed act grants an exemption from the substance restrictions in Annex II to the RoHS Directive, to be listed in its Annex IV (on exemptions specific to medical devices and monitoring and control instruments), for the use of DEHP in specific applications.

The instrument is a delegated directive, as provided for in the RoHS Directive and meeting the relevant requirements of its Article 5(1)(a).

The objective of the delegated directive is to contribute to the protection of human health and the environment, and harmonise provisions for the functioning of the internal market in the field of EEE, by allowing the use of otherwise banned substances for specific applications, in line with the RoHS Directive and the procedure established therein for the adaptation to scientific and technical progress of its Annexes III and IV.

The delegated directive has no implications for the EU budget.

**COMMISSION DELEGATED DIRECTIVE (EU) .../…**

**of XXX**

**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 in dialysate fluids**

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 Annexes III and 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 in 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

[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).

Article 5(7) of Directive 2011/65/EU. The comments received during those consultations were made publicly available on a dedicated website.

(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 adoption of this Directive], in accordance with Article 5(2), second 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,

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 [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 communicate the text of those provisions to the Commission forewith.

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 that 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*.

[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).

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels,

*For the Commission*
*The President*
*Ursula von der Leyen*