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), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices

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), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

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), DEHP, BBP, DBP and DIBP.

Annexes III and IV to the RoHS Directive list the materials and components of EEE for specific applications exempted from the substance restrictions in Article 4(1). DEHP, BBP, DBP and DIBP were added to the list of restricted substances in Annex II by Commission Delegated Directive (EU) 2015/863[2] and will be prohibited in medical devices covered by the Directive from 22 July 2021. The restriction will not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of medical devices, including *in vitro* medical devices, placed on the market before that date.

Article 4(4) of the RoHS Directive excludes spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before certain dates. Article 4(5) allows the reuse of spare parts recovered from medical devices placed on the market before 22 July 2014 (22 July 2016 in the case of *in vitro* diagnostic medical devices) and used in EEE placed on the market before 22 July 2024 (22 July 2026), provided that the reuse takes place in auditable closed-loop business-to-business return systems and is notified to the customer.

Article 5 of the Directive 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.

[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).

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.

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 an application for a new exemption in Annex IV to allow the continued placing on the market of spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices, containing > 0.1% DEHP, BBP, DBP and DIBP by weight in homogeneous materials. According to the applicants, the reuse of spare parts containing these substances would take place in auditable closed-loop business-to-business return systems and each reuse would be notified to the consumer.

The requested exemption goes beyond what is already allowed under the RoHS Directive (Article 4(4) and (5), Annex II), as it would involve extending the periods of the exclusions for spare parts and allowing the use of the four substances in spare parts from medical devices that have not previously been placed on the EU market.

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, included 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. 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, BBP, DBP and DIBP are used as additives in polymers, adhesives, sealants, paints and lacquers to improve the properties (e.g. flexibility) of equipment (e.g. cable insulation, rubber seals) in medical devices, including *in vitro* diagnostic medical devices;

---

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

5 For the final report of the study, 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.

- the market for recovered spare parts for medical equipment is a global one and spare parts are collected globally for refurbishment and further distribution. Therefore, it is not feasible to distinguish spare parts by their market of origin and to determine the concentration of phthalates in a non-destructive way. Furthermore, the existing spare parts provisions do not cover the global distribution of recovered spare parts for medical equipment;
- the substitution of the restricted phthalates has been assessed to be both scientifically and technically practicable. However, manufacturing new parts not containing the substances, rather than reusing existing spare parts, produces carbon dioxide emissions, introduces heavy metals into the market and leads to the premature generation of hazardous and non-hazardous waste;
- overall, the total negative environmental, health and consumer safety impacts of substituting the four phthalates in spare parts are likely to outweigh the total benefits.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The evaluation results show that granting this exemption would not weaken the environmental and health protection afforded by the REACH Regulation.

Furthermore, the exemption request meets at least one of the criteria in Article 5(1)(a) of the Directive: the total negative environmental, health and consumer safety impacts of substitution are likely to outweigh the total environmental, health and consumer safety benefits.

The 7-year validity period for the exemption is not expected to have adverse impacts on innovation and due to a long lifetime of MRI devices, phthalate-containing spare parts will be needed in the following years. 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, BBP, DBP and DIBP in specific applications.

The instrument is a delegated directive, as provided for by 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 the 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), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the repair or refurbishment of medical devices

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 that Directive. That restriction does not apply to certain exempted applications listed in Annexes III and IV to that Directive.

(2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in its Annex I.

(3) By Commission Delegated Directive (EU) 2015/863[2], bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) were added to the list of restricted substances referred to in Annex II to Directive 2011/65/EU.

(4) Commission Delegated Directive (EU) 2015/863 provides that the restriction of DEHP, BBP, DBP and DIBP is not to apply to spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of medical devices, including *in vitro* medical devices, placed on the market before 22 July 2021.

(5) 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, BBP, DBP and DIBP in spare parts recovered from and used for the repair or refurbishment of medical devices, including *in vitro* diagnostic medical devices ('the requested exemption').

(6) The evaluation of the exemption application concluded that the total negative environmental and health impacts of substituting refurbished parts containing DEHP, BBP, DBP and DIBP with new substance-free refurbished parts are likely to outweigh the total environmental and health benefits.The evaluation included stakeholder consultations required by Article 5(6) of the Directive 2011/65/EU. The comments

[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).

received during those consultations were made publicly available on a dedicated website.

(7) In order to ensure a high level of protection for the environment, health and consumer safety, reuse should take place in auditable closed-loop business-to-business return systems and reuse of spare parts should be notified to the customer.

(8) The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH)[3] and does not weaken the environmental and health protection afforded by it.

(9) It is therefore appropriate to grant the requested exemption by including the applications covered by it in Annex IV to Directive 2011/65/EU.

(10) The requested exemption should be granted for a duration of 7 years starting from [the date of the adoption of this Directive], in accordance with the second 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.

(11) 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 forthwith.

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*.

[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), 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