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 lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections

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 ('the RoHS Directive')[1] as regards an exemption for specific applications containing lead.

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).

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) of the Directive. Article 5 provides for Annexes III and IV to be adapted to scientific and technical progress (on 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)[2] and if any of the following conditions is fulfilled:

– the elimination or substitution of the substance 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, must 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 impact 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 from economic operators to grant or renew exemptions according to Article 5(3) and Annex V to the RoHS Directive[3].

---

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).

3 The list is available at http://ec.europa.eu/environment/waste/rohs_eee/adaptation_en.htm.

On 25 March 2019, the Commission received one application for a new entry in Annex IV to the RoHS Directive. The requested exemption concerns the use of lead in superconducting material and the related electrical connections in specific devices.

In August 2019, the Commission launched a study[4] to evaluate how this new exemption was being applied and carry out the required technical and scientific assessment. The study, which included an eight-week public stakeholder consultation, finished in July 2020. Information about the consultation was provided on the project website[5], although no contributions were received in response to the consultation.

The Commission consulted the Member State expert group for delegated acts under the RoHS Directive on 23 February 2021. Some experts agreed with the drafts that were presented, while many experts did not comment. The Commission carried out all the requisite procedural steps relating to exemptions from the restrictions on substances under Articles 5(3) to 5(7)[6], and the Council and the European Parliament were notified of all activities in this context.

The technical and scientific assessment report highlighted that:

- Lead can be added to bismuth strontium calcium copper oxide material (lead-doped BSCCO). This material can be used in superconducting components like cables and wires which create an electromagnetic circuit for medical devices or (industrial) monitoring and control instruments (e.g. magnetic resonance imaging devices (MRI) or nuclear magnetic resonance (NMR) spectrometers). Tin-lead solder is used to connect these superconducting components.
- The addition of lead to BSCCO provides technical and functional advantages such as stronger magnetic fields and higher critical temperature, which cannot be achieved without the use of lead.
- For the connections, there is no other alternative material available for tin-lead solder with the same reliable properties (e.g. sufficient ductility and low electrical resistivity at low temperatures).
- The elimination or substitution of lead is scientifically and technically not practicable without loss of performance. Substituting or eliminating lead in the superconducting material and the related solders is not currently, or in the foreseeable future expected to be, scientifically or technically practicable.
- The technical and functional advantages can result in higher resolution images for medical diagnosis or for research and innovation, and they allow more stable operation of NMR or MRI. The total amount of lead placed on the market is expected to be around 15.5 kg per year.
- Lead-doped BSCCO will likely be used for stronger magnetic field strengths, whereas lead-free technology can be used to generate lower magnetic field strengths for less demanding conditions. Excluding lower field strengths from the scope of the exemption is not commensurate, as it would potentially limit innovation for lead-doped BSCCO (e.g. smaller devices) and the economically more favourable alternatives in the lower field strengths.

---

4 The final report from the study is available at https://op.europa.eu/en/publication-detail/-/publication/f44f2383-dd0a-11ea-adf7-01aa75ed71a1/language-en/format-PDF/source-146144383.

5 Consultation period: 3 December 2019 to 27 January 2020 (https://rohs.exemptions.oeko.info/).

6 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 Inter-institutional Registry of Delegated Acts at https://webgate.ec.europa.eu/regdel/#/home.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The evaluation results show that granting the exemption would not weaken the environmental and health protection afforded by the REACH Regulation, in accordance with Article 5 of Directive 2011/65/EU.

One of the relevant criteria specified in Article 5(1)(a) is met, namely that the 'elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable'.

Therefore, the exemption is to be granted and an expiry date is to be set.

The proposed act grants an exemption from the substance restrictions in Annex II to Directive 2011/65/EU, to be listed in Annex IV, for the use of lead in BSCCO superconductor cables and wires and in the related electrical connections.

As no reliable substitutes are expected in the near future, it is appropriate to grant the exemption until 30 June 2027. The granted validity period is not expected to have adverse effects on innovation.

The legal instrument is a delegated directive, as provided for in Directive 2011/65/EU and meeting the relevant requirements of Article 5(1)(a) of the Directive.

The objective of the delegated directive is to help protect human health and the environment, and harmonise provisions for the functioning of the single 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 adapting Annexes III and IV to the Directive to scientific and technical progress.

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 lead in bismuth strontium calcium copper oxide superconductor cables and wires and lead in their electrical connections

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, which are specific to medical devices and monitoring and control instruments, and are listed in Annex IV to that Directive.

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

(3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.

(4) On 25 March 2019, 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 lead in bismuth strontium calcium copper oxide superconductor for use in cables and wires and lead in related electrical connections to other EEE components ('the requested exemption'). Lead-doped BSCCO can be used to create superconducting magnetic circuits for medical devices and monitoring and control instruments.

(5) The evaluation of the requested exemption 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.

(6) Lead-containing solders are used to connect the superconducting wires and cables to other EEE components. There is currently no lead-free alternative available on the market that would provide a sufficient level of reliability for applications, where properties such as ductility and low electrical resistivity at low temperatures are required.

(7) The evaluation of the requested exemption, which included a technical and scientific assessment study[2], concluded that the addition of lead to BSCCO provides technical and functional advantages that cannot be achieved without the use of lead. Those

[1] OJ L 174, 1.7.2011, p. 88.

[2] Study to assess seven exemption requests relating to Annex III and IV to Directive 2011/65/EU.

technical and functional advantages consist in higher resolution images for medical diagnosis or for research and innovation, and allow a more stable operation mode of the relevant applications. The addition of lead to BSCCO makes it possible to produce more efficient and reliable equipment, which is beneficial for health care and innovation.

(8) It is currently not possible to substitute or otherwise eliminate lead in the superconducting material and the related solders with the same technical performance, nor is it expected to be so in the foreseeable future. The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council[3] and does not weaken the environmental and health protection afforded by it.

(9) It is, therefore, appropriate to grant the requested exemption.

(10) The technical advantages of the lead-doped BSCCO-material have the potential to promote improvements and innovation in medical diagnostics and in research. The duration of the exemption is unlikely to have adverse impacts on innovation. Therefore, it is appropriate to grant the exemption for an extensive validity period, in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU.

(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 [OP please insert the date: 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 forthwith communicate the text of those provisions to the Commission.

   They shall apply those provisions from [OP please insert the date: 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, 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*.

[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/E EC 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